DISSERTATION ON

CORRELATING PREOPERATIVE RADIOLOGICAL (HRCT AND MRI-DWI) IMAGING IN PATIENTS WITH SQUAMOUS EPITHELIAL CHRONIC OTITIS MEDIA WITH PEROPERATIVE FINDINGS

Dissertation submitted in partial fulfillment of the regulations for the award of the degree of

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MADRAS MEDICAL COLLEGE

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THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY
CHENNAI

APRIL 2016

BONAFIDE CERTIFICATE

This is to certify that this dissertation is a bonafide record of work done by Dr.C.U.SAVIDHA on **CORRELATING PREOPERATIVE RADIOLOGICAL (HRCT AND MRI-DWI) IMAGING IN PATIENTS WITH SQUAMOUS EPITHELIAL CHRONIC OTITIS MEDIA WITH PEROPERATIVE FINDINGS**, during her M.S. ENT course from April 2013 to April 2016 at the Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai. He is appearing for his M.S. Branch – IV Degree Examination in April – 2016 and his work has been done with partial fulfillment of the regulations of The TamilNadu Dr. M.G. R Medical University, Chennai. I forward this to The TamilNadu Dr. M.G. R Medical University, Chennai, TamilNadu, India.

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CERTIFICATE

This is to certify that this dissertation titled **CORRELATING PREOPERATIVE RADIOLOGICAL (HRCT AND MRI-DWI)IMAGING IN PATIENTS WITH SQUAMOUS EPITHELIAL CHRONIC OTITIS MEDIA WITH PEROPERATIVE FINDINGS** been carried out independently and satisfactorily by Dr.SAVITHA C U in Institute Of Otorhinolaryngology, Madras Medical College and Rajiv Gandhi General Hospital, Chennai under my supervision and guidance. All the case studies, results and observations and their interpretation of the thesis has been done by the candidate and periodically checked by me .she is appearing for her M.S.ENT branch IV degree examination in April 2016 and her work has been done with partial fulfillment of the regulations of The Tamilnadu Dr.M.G.R Medical University, Chennai, Tamilnadu,India

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DECLARATION

I, **DR.C.U.SAVIDHA,** solemnly declare that this dissertation entitled on **CORRELATING PREOPERATIVE RADIOLOGICAL (HRCT AND MRI-DWI)IMAGING IN PATIENTS WITH SQUAMOUS EPITHELIAL CHRONIC OTITIS MEDIA WITH PEROPERATIVE FINDINGS** is a bonafide work done by me in Upgrade Institute Of Otorhinolaryngology, Madras Medical College and Rajiv Gandhi General Hospital , Chennai during the period of 2013 to 2016 under the guidance of **Prof.Dr.R.MUTHUKUMAR M.S.D.L.O.,** Professor, Institute Of Otorhinolaryngology, Madras Medical College and Rajiv Gandhi General Hospital, Chennai – 3 and submitted to The Tamilnadu Dr.M.G.R. Medical University , Guindy , Chennai – 32 in the partial fulfillment of the regulations for the award of the M.S.E.N.T ., (Branch IV).

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ABBREVIATIONS

HRCT	-	High Resolution Computerized Tomography
MRI	-	Magnetic Resonance Imaging
DWI	-	Diffusion Weighted Images
PTA	-	Pure Tone Audiometry

CONTENTS

Introduction

INTRODUCTION

ANATOMY OF MASTOID BONE:

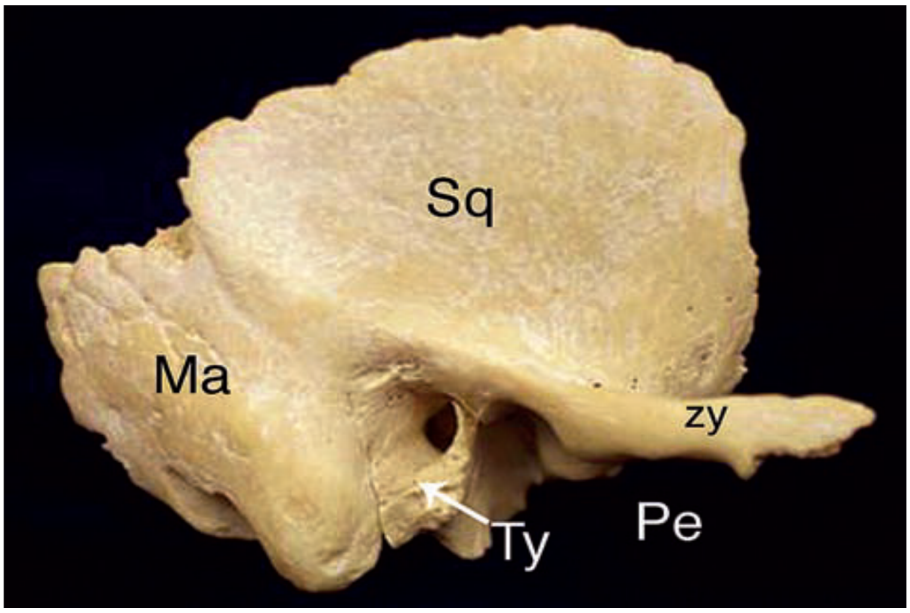
The temporal bone anatomically consists of four bones: the mastoid, petrous, squamous, and tympanic. The pneumatized portion of the temporal bone consists of a continuous air cell tract that includes the Eustachian tube, the middle ear, and the mastoid air cells. From the anatomical point of view, the mastoid contains one large air cell—the *antrum*—and the periantral cells that communicate with it. . The mastoid has a triangular shape. The anatomical limits of the mastoid are the *tegmen* superiorly, the *posterior bony canal* anteriorly, and the *sigmoid sinus* posteriorly.

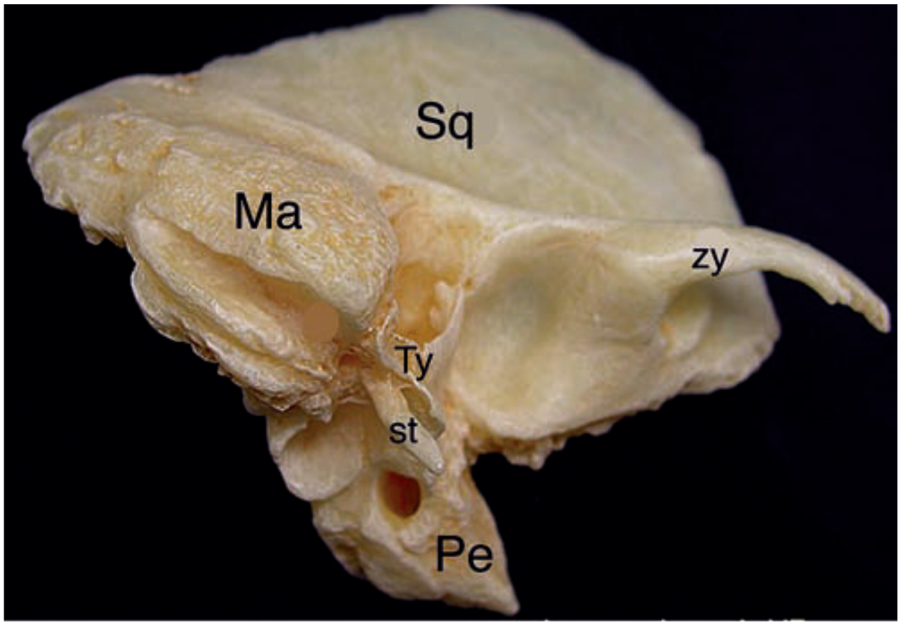
The cellularity of the mastoid varies among individuals and can be well developed ("pneumatized"), diploic (marrow containing), or sclerotic (dense bone). Every mastoid, no matter how poorly developed, has a single large air cell called the *antrum* Lateral to the antrum is a thin plate of bone named the *Korner septum*. Anatomically, the Korner septum, also named the petrosquamosal septum, is an embryonic fusion plane of the squamous and petrous bones. At the base of the antrum is a dome of dense ivory bone formed by the *lateral* (or horizontal) *semicircular canal*

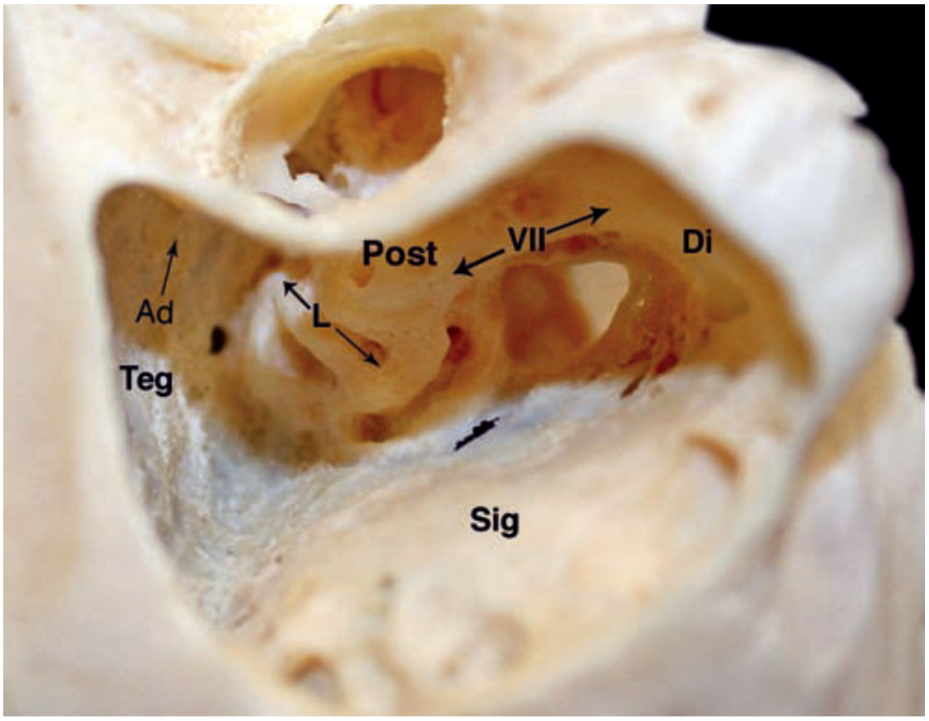
This is the key surgical landmark in the temporal bone. The antrum communicates with the *epitympanum* (attic) superiorly, through the *aditus ad antrum*. The *fossa incudus* is the space just anterior and inferior to the aditus that houses the body of the incus. The mastoid tip is the most dependent group of air cells and is bisected by the *digastric ridge*, the indentation formed externally by the posterior belly of the digastric muscle forming the digastric groove.

The incus points to the mastoid (vertical) segment of the *facial nerve*. The pneumatized cell tract just lateral to the mastoid segment of the facial nerve is called the *facial recess*. The facial recess is bounded laterally by the *chorda tympani* nerve, superiorly by the incus, and medially by the facial nerve. The facial recess can be opened surgically to create a communication between the mastoid and the middle ear. The sigmoid sinus forms the posterior limit of the mastoid

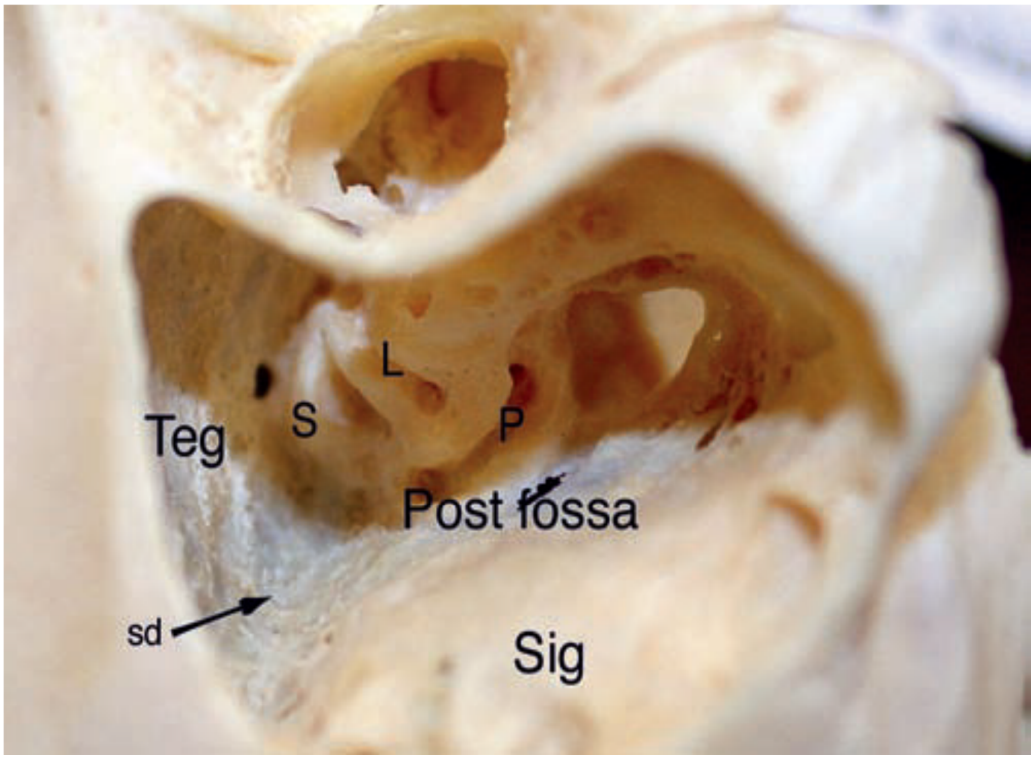
LEFT TEMPORAL BONE







Mastoid anatomy, as shown in a dry temporal bone dissection of the right ear and turned into a surgical position. The tegmen mastoideum (Teg), posterior bony canal wall (Post), and sigmoid sinus (Sig) form the boundaries of the surgical cavity. At the base of the mastoid antrum sits the lateral semicircular canal (L), which is an important landmark for the facial nerve (VII). The digastric ridge (Di) bisects the mastoid tip and is another landmark for the facial nerve. The aditus (Ad) is the communication from the antrum to the epitympanum.



The solid angle of bone is formed by the lateral (L), superior (S), and posterior (P) semicircular canals. The sigmoid sinus (Sig) joins the tegmen plate (Teg) at the sinodural angle (sd). The posterior fossa dural plate (Post fossa) lies anterior to the sigmoid sinus

TYMPANIC DIAPHRAGM:

Tympanic diaphragm is the term introduced by Proctor to define the obstacles within the tympanic isthmus and attic.These obstacles are tympanic folds and ligaments running between the surrounding bony structures and the incus body and malleus head.The tympanic diaphragm divides the attic from mesotympanum. The tympanic diaphragm is a common site for impairment of ventilation to the antrum.

The most posterior parts of posterior isthmus and anterior isthmus are open for ventilation. All the other passages are obstructed by the various mucosal folds that Proctor considers to be congenital structures and remnants of development.

MUCOSAL FOLDS

The folds divide the attic space into various compartments. They are located in both lateral compartment and medial compartment

The lateral incudal fold connects the lateral attic wall and body of the incus. It extends posteriorly to the posterior incudal ligament

The anterior malleolar fold of von Troltsch is located between the anterior surface of the malleus head, the anterolateral bony wall of the attic, and the anterior malleolar ligament

The superior malleolar fold extends between the superior surface of the malleus head and the superior attic wall and in the same plane as superior malleolar ligament.

The superior incudal folds extends like superior incudal ligament between the superior aspects of the incus body and the superior attic wall

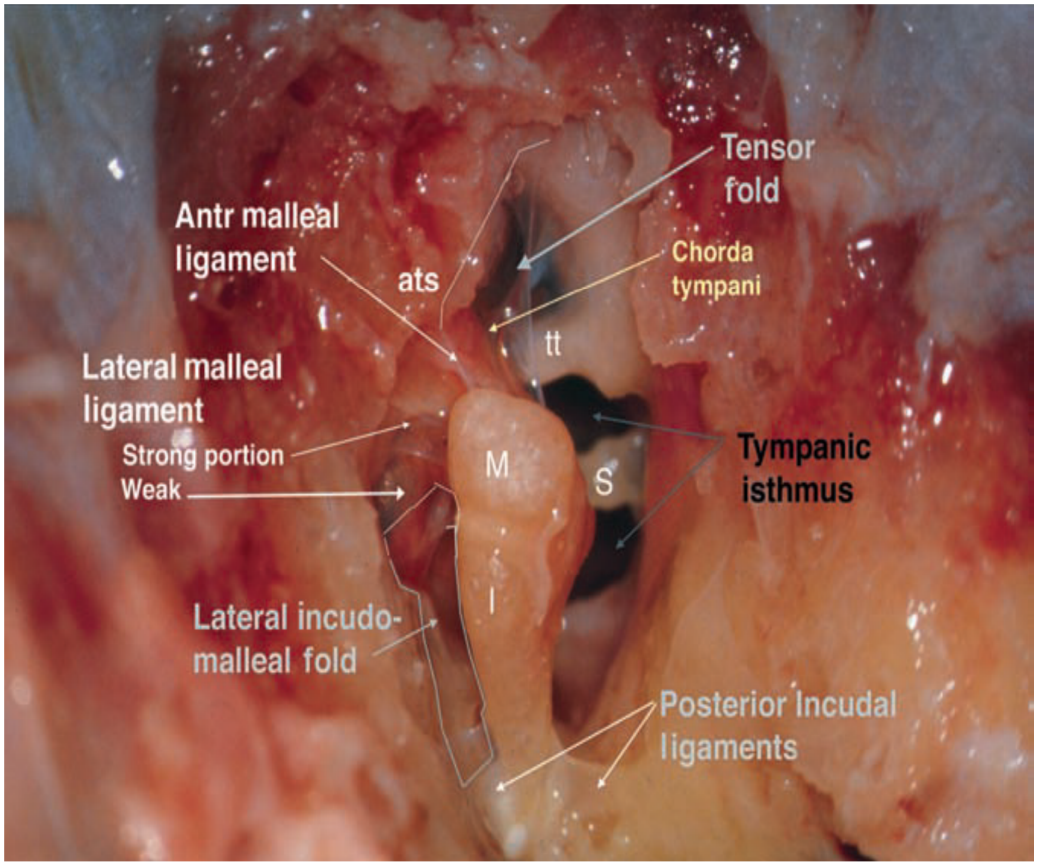
The medial incudal fold is located between the long process of incus and the tendon of the stapedial muscle as far as pyramidal eminence

The lateral malleolar fold goes from the neck of the malleus up to the scutum forming the superior border of Prussak's space

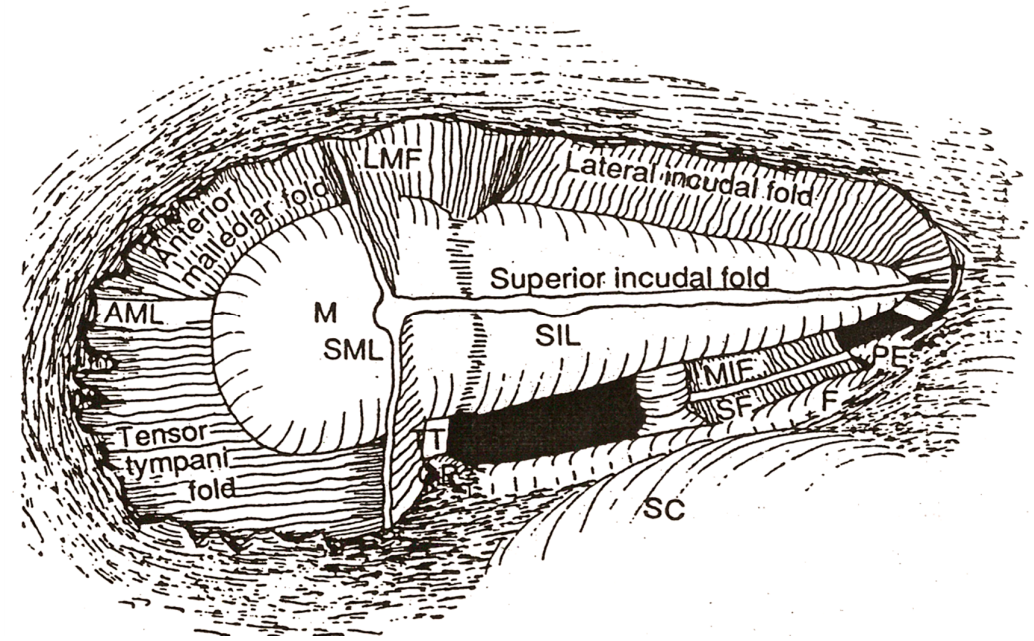
The interossicular fold extends berween the malleus handle and long process of the incus

The anterior malleolar ligament extends from the long process of the malleus toward the anterior attic wall.

The tensor tympani fold occupies the window between the tensor tympani tendon, the anterior bony plate of the attic wall, the tensor tympani eminence and the anterior malleolar ligament



Epitympanic dissection showing the structures that form the epitympanic diaphragm.



LMF - lateral malleolar fold

MIF – medial incudal fold

SF – stapedial fold

AML – anterior malleolar ligament

M – malleus head

SML – superior malleolar ligament

SIL – superior incudal ligament

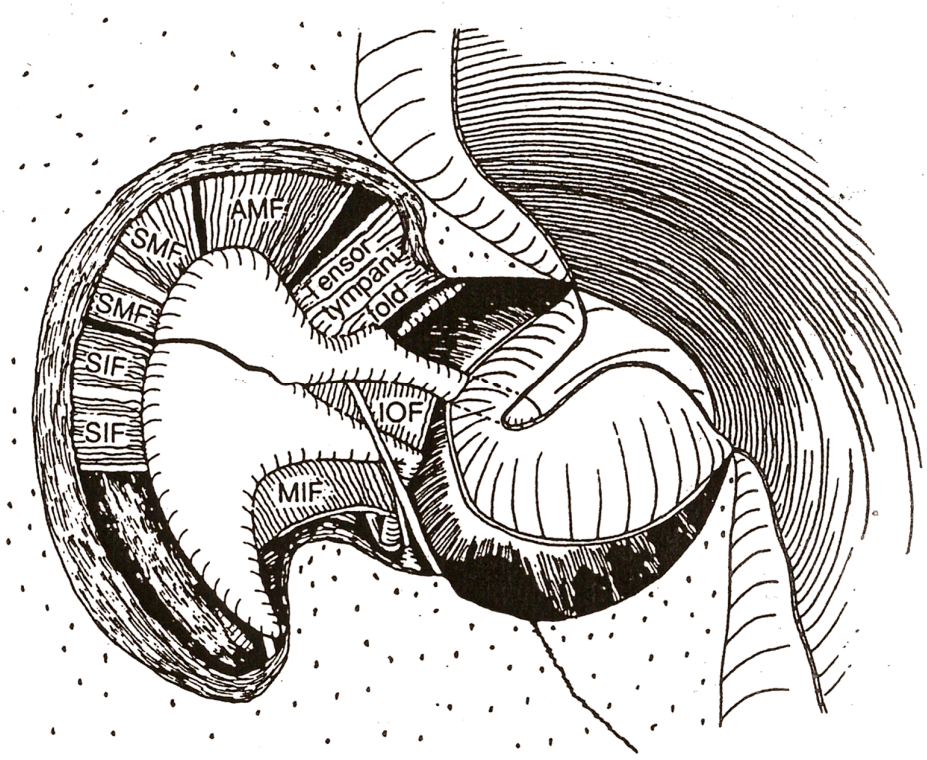
CP – cochleariform process

F – facial nerve

PE – pyramidal eminence

SC – lateral semicircular canal

TT – tensor tympani tendon



SIF – superior incudal fold

SMF – superior malleolar fold

AMF – anterior malleolar fold

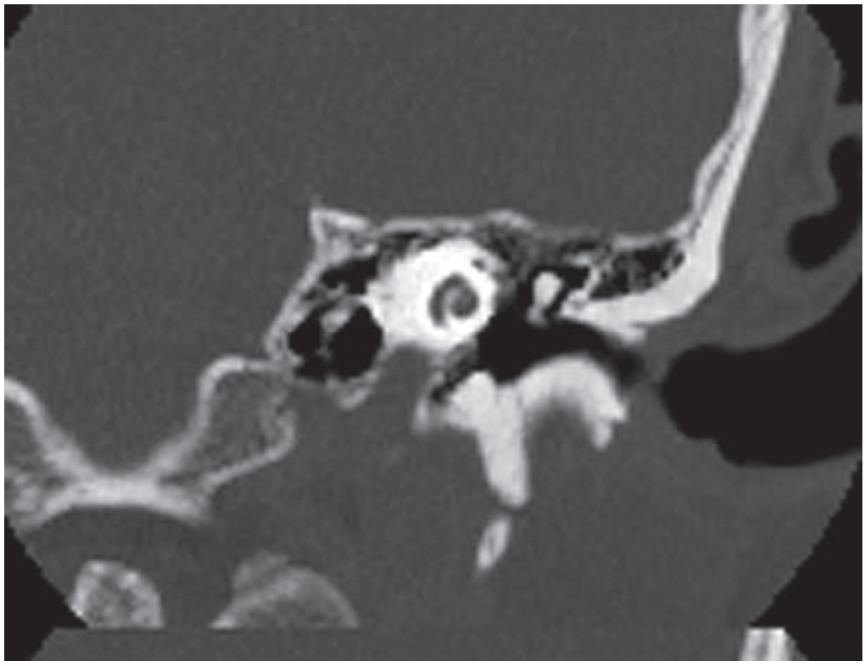
MIF – medial incudal fold

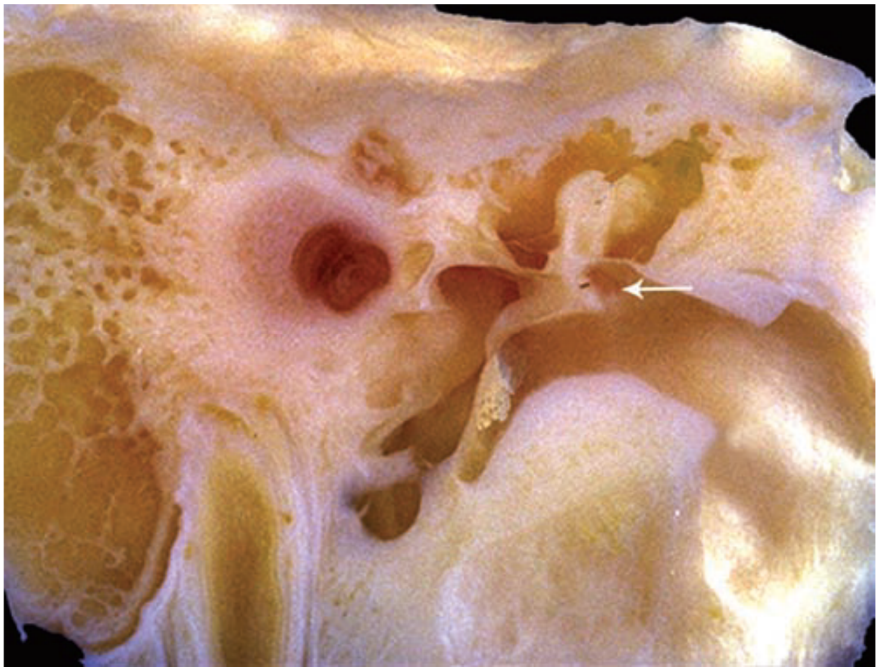
IOF – inter ossicular fold

Prussak's space:

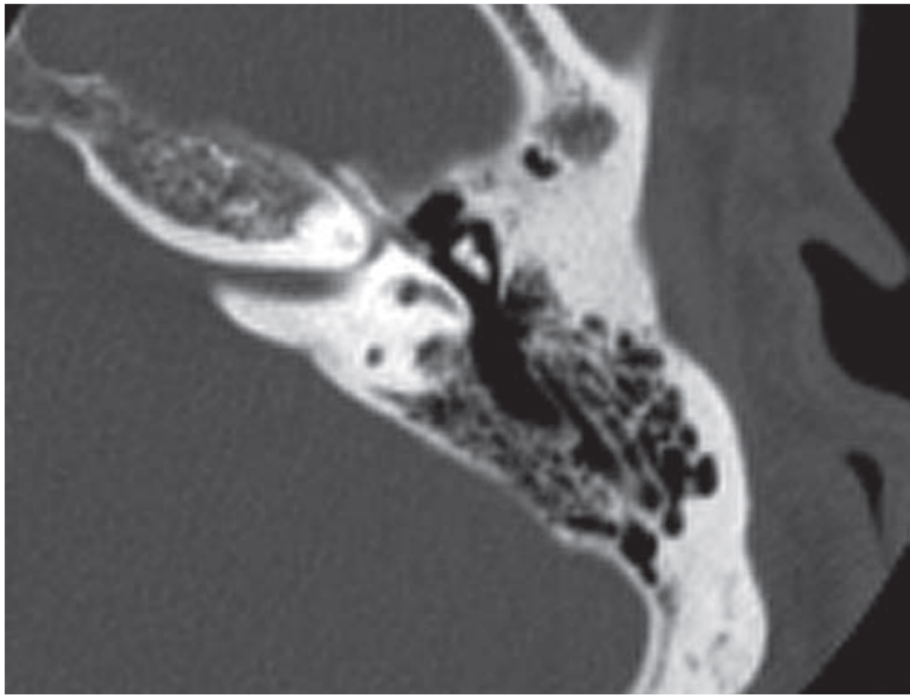
Prussak's space lies between Shrapnell's membrane amd the lateral malleolar ligament. The medial border is formed by the short process and the neck of the malleus and the lateral border is the bony annulus of the Shrapnell's membrane region. From the neck of the malleus the anterior malleolar fold and the anterior ligament arise, demarcating Prussak's space anteriorly. Ventilation of Prussak's space is possible only posteriorly above the posterior malleus fold which arises together with the posterior malleolar ligament from posterior aspect of the malleus neck, and attaches to the bony annulus. Between the posterior malleolar fold and the fibrous annulus and related to the most superior aspect of pars tensa, a small pouch, the von Troltsch posterior malleus pouch, is located. The ventilation of attic proceeds from the Eustachian tube around the tendon of tensor tympani muscle and through the anterior tympanic isthmus and from here the anterior and superior attic and antrum ventilated.

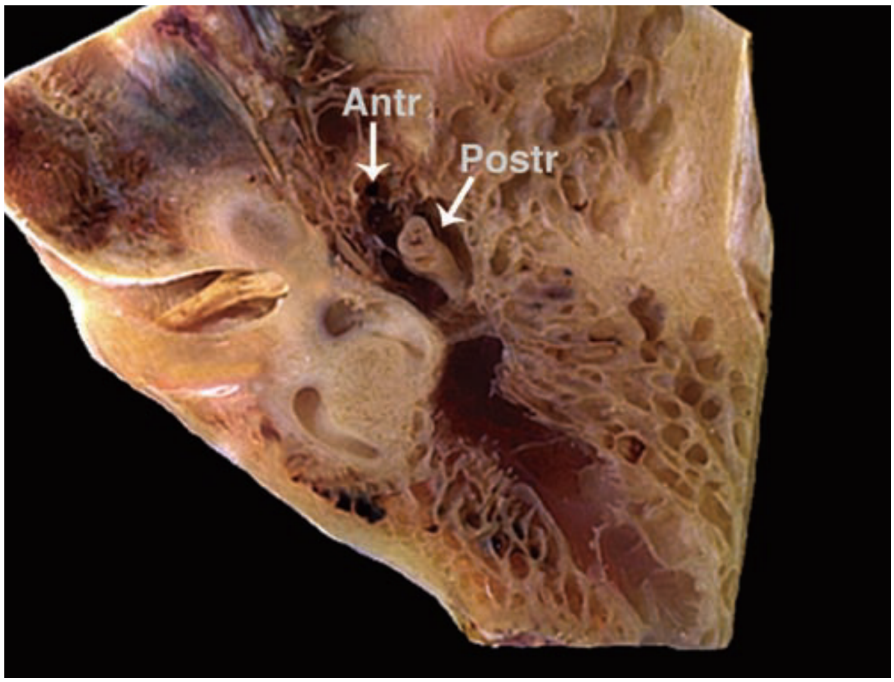
Cholesteatoma from the Shrapnell's membrane region may slip into Prussak's space and develop anterior to the malleus handle. It can remain hidden for a long time and this gives Prussak's space its clinical importance.





Coronal CT image and (B) temporal bone sectioned in coronal plane, showing the lateral epitympanic, or Prussak's space (*horizontal arrow*).





Axial CT and temporal bone sectioned in axial plane, showing anterior (*Antr*) and posterior (*Postr*) epitympanic spaces.

CHOLESTEATOMA :

It is a growth of keratinizing squamous epithelium originating from the external layer of the tympanic membrane or ear canal that invades the middle ear cleft (the air-containing space that is medial to the plane of the tympanic membrane). Cholesteatoma has two components—the acellular keratin debris, which forms the contents of the sac, and the matrix, which forms the sac itself. The cholesteatoma matrix consists of an inner layer of keratinizing squamous epithelium and an outer layer of subepithelial connective tissue (perimatrix). The matrix is the biologically active component of the cholesteatoma the epithelial layer produces the keratin, whereas the subepithelial layer contains mesenchymal cells that can resorb bone and that give the cholesteatoma its invasive properties.

Cholesteatoma is a destructive process that invades middle ear and causes damage by passive growth and active destruction of adjacent bony structures. Cholesteatoma first forms when keratinizing squamous epithelium from the external canal traverses the plane of the tympanic membrane. Once this plane is breached, the cholesteatoma sheds squamous debris into its center and grows passively to occupy the middle ear cleft (which consists of the Eustachian tube, middle ear, and mastoid air cell system). But cholesteatoma is not merely a passive process; it is actively invasive. The cholesteatoma matrix produces proteolytic

(collagenolytic) enzymes that can erode bone. Cholesteatoma can also become secondarily infected leads to pyogenic osteitis leading to malodorous discharge..

Classification:

Cholesteatoma can be

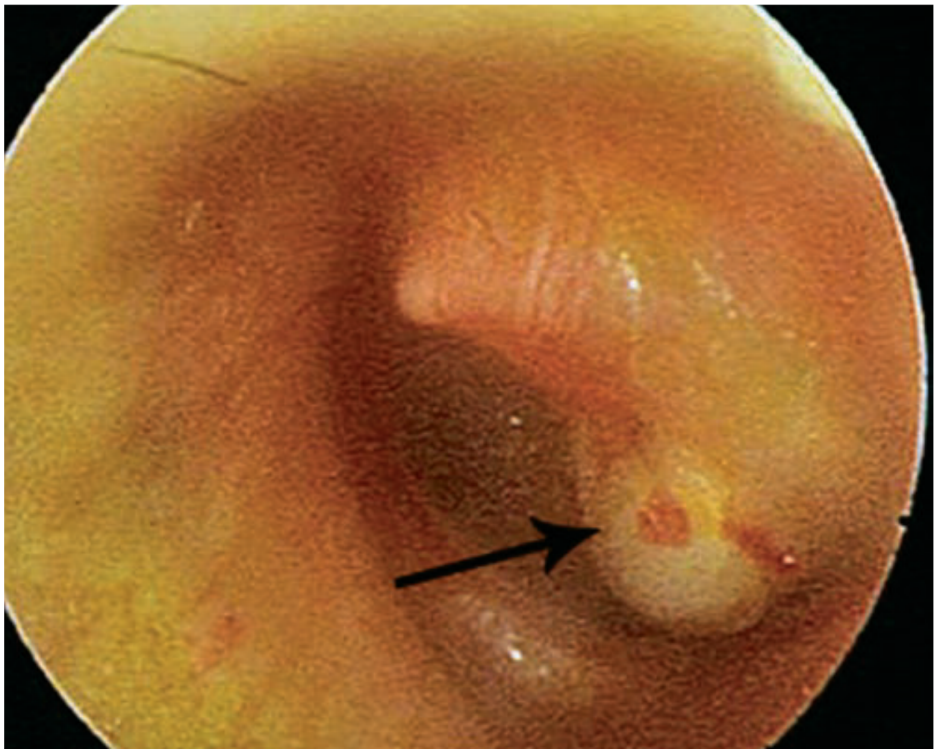
Congenital: Due to trapping of epithelium during development

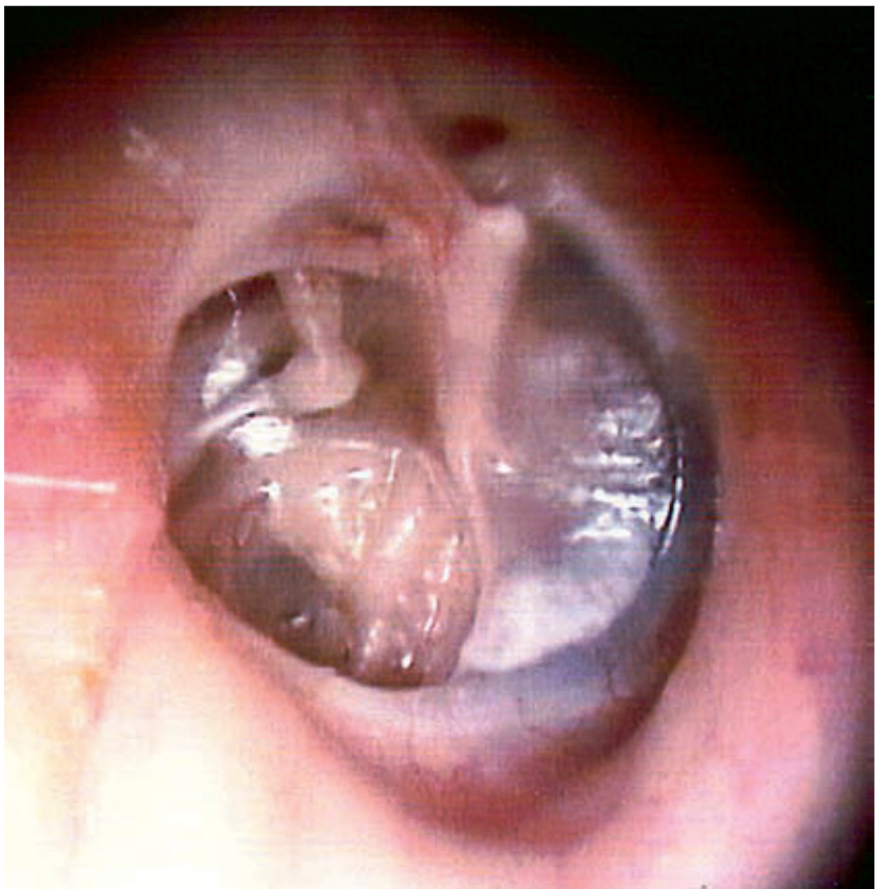
Acquired:

Primary: occurs in the ear where there is no previous history of ear discharge from the ear.

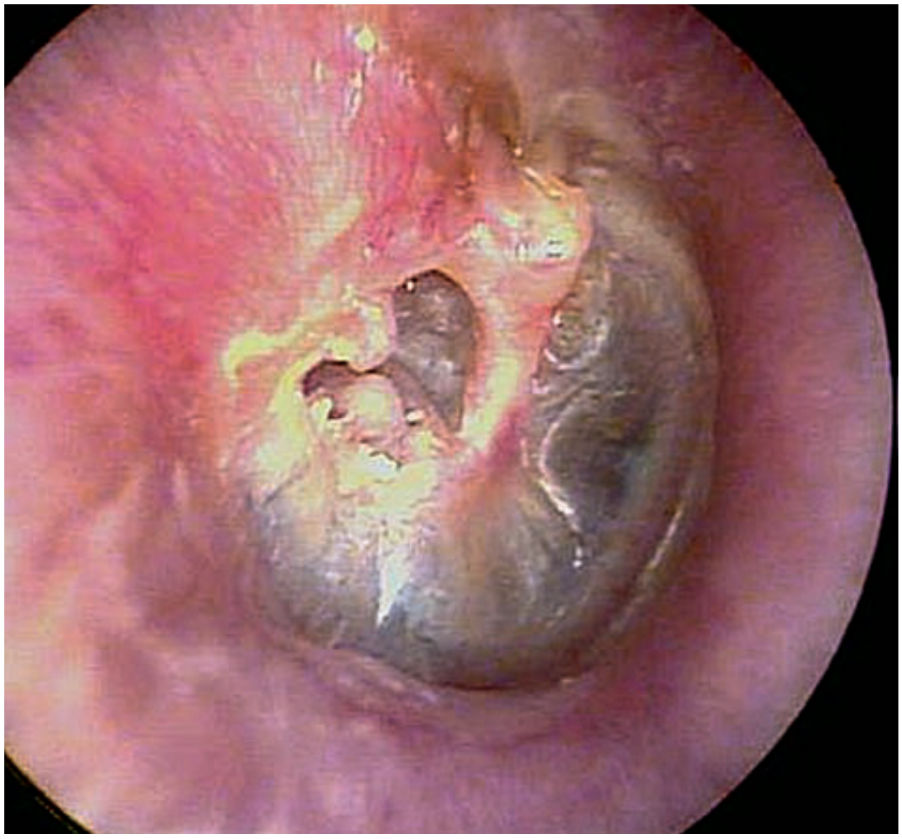
Secondary: cholesteatoma occurs in already diseased ear

Congenital cholesteatomas are epithelial rests that become entrapped in the middle ear cleft during embryogenesis. They appear as a keratin sac behind an intact tympanic membrane. They are believed to occur from failure of the normal involution of embryonic epidermoid tissue, this squamous epithelium trapped within the middle ear during embryogenesis is most commonly attached to the anterior border of the tensor tympani muscle but may also attached to stapedia tendon

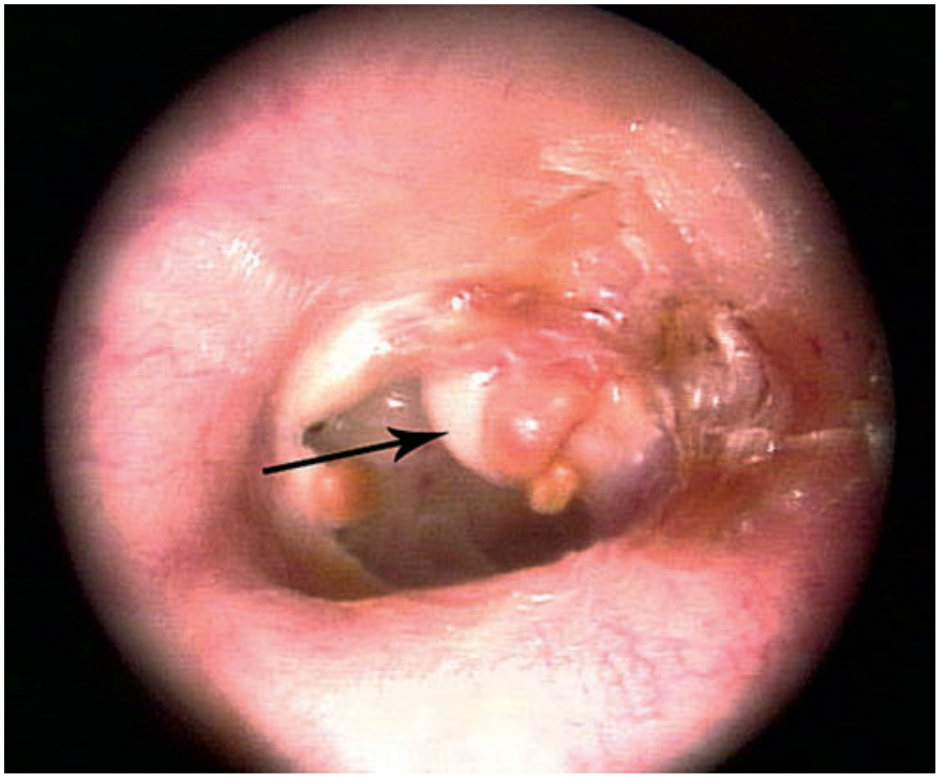




Cholesteatoma most commonly arises from a retraction pocket of the pars flaccida or the pars tensa



Over time, the retraction pocket can become infected, invade the middle ear cleft, erode bone, and liberate keratin. A retraction pocket cholesteatoma is termed primary acquired.



Cholesteatoma may also arise from migration of Keratinizing squamous epithelium into the middle ear space from a tympanic membrane perforation (*arrow*). This is termed *secondary acquired cholesteatoma*

Cholesteatoma can also be classified according to their site as follows

Attic cholesteatoma:

Retraction of Shrapnell's membrane and extends into lateral attic where it is attached lateral to the malleus head and incus body.

Sinus tympani cholesteatoma:

Retraction or perforation of the posterosuperior part of pars tensa, surrounds the stapes and extends into the tympanic sinuses. The long process of the incus is usually resorbed and the cholesteatoma extend medial to the incus body upto the attic

Tensa retraction cholesteatoma:

Retraction of the entire pars tensa. It is adherent to the promontory, hypotympanum, tympanic sinuses and tubal orifice and can continued under the malleus head and incus body up into the attic

THEORIES OF CHOLESTEATOMA:

Retraction pocket theory:

Eustachian tube obstruction will produce negative pressure in the middle ear cavity as a result there will be formation of a retraction pocket .this will produce accumulation of the desquamated epithelium and pressure necrosis of the tympanic membrane forming cholesteatoma of the middle ear this theory holds good in explaning the primary acquired cholesteatoma

Theory of migration :

Skin of the external auditory meatus will migrate to the middle ear cavity through the tympanic membrane perforation leading to secondary acquired cholesteatoma

Metaplasia theory :

Because of recurrent or chronic infection normal columnar epithelium turns into squamous epithelium by metaplasia

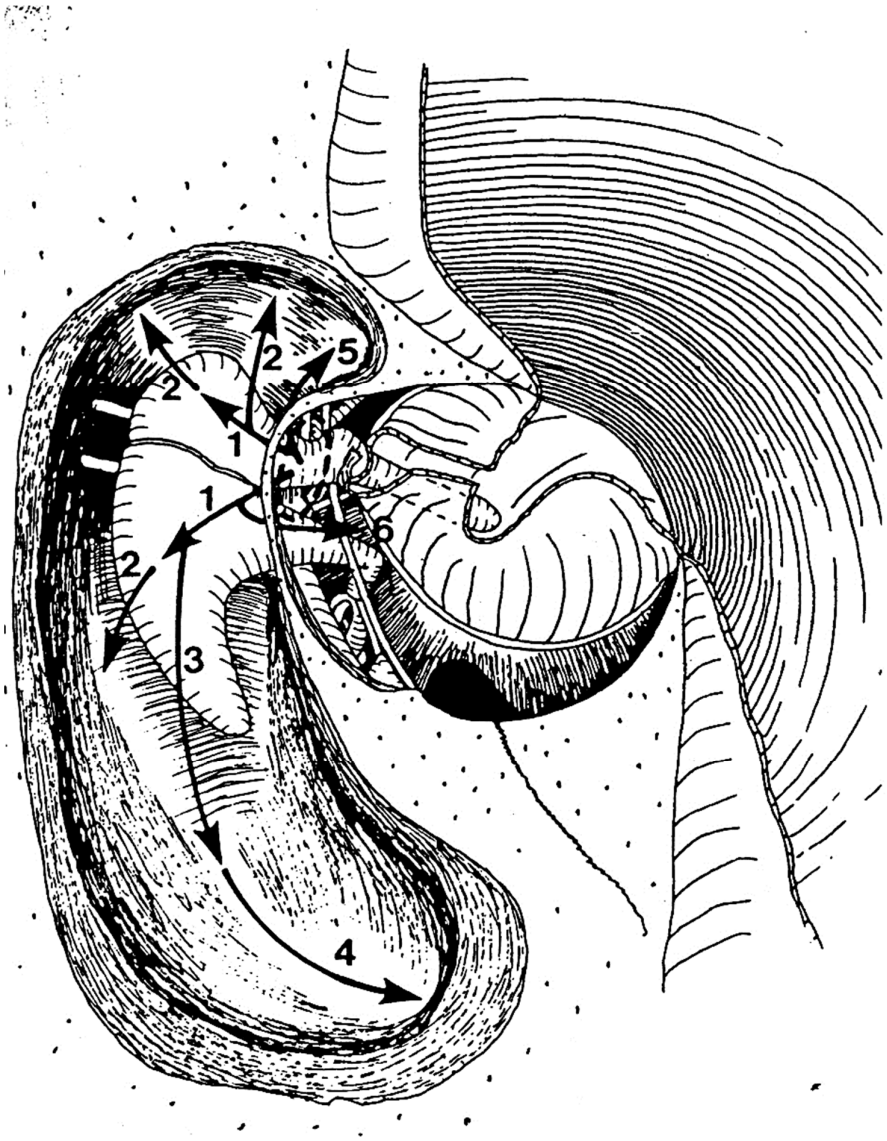
Implantation theory:

At the time of middle ear surgery squamous epithelium may get implant

Modes of spread:

Attic cholesteatoma – lateral extension

1. From the Shrapnell's membrane the cholesteatoma extends laterally on the incus body and malleus head
2. then up to the anterior, superior and posterior attic
3. from there to the aditus ad antrum and
4. In to the mastoid process.
5. Some rare cholesteatoma extend anteriorly direct into the Prussak's space or
6. along the malleus neck into the tympanic cavity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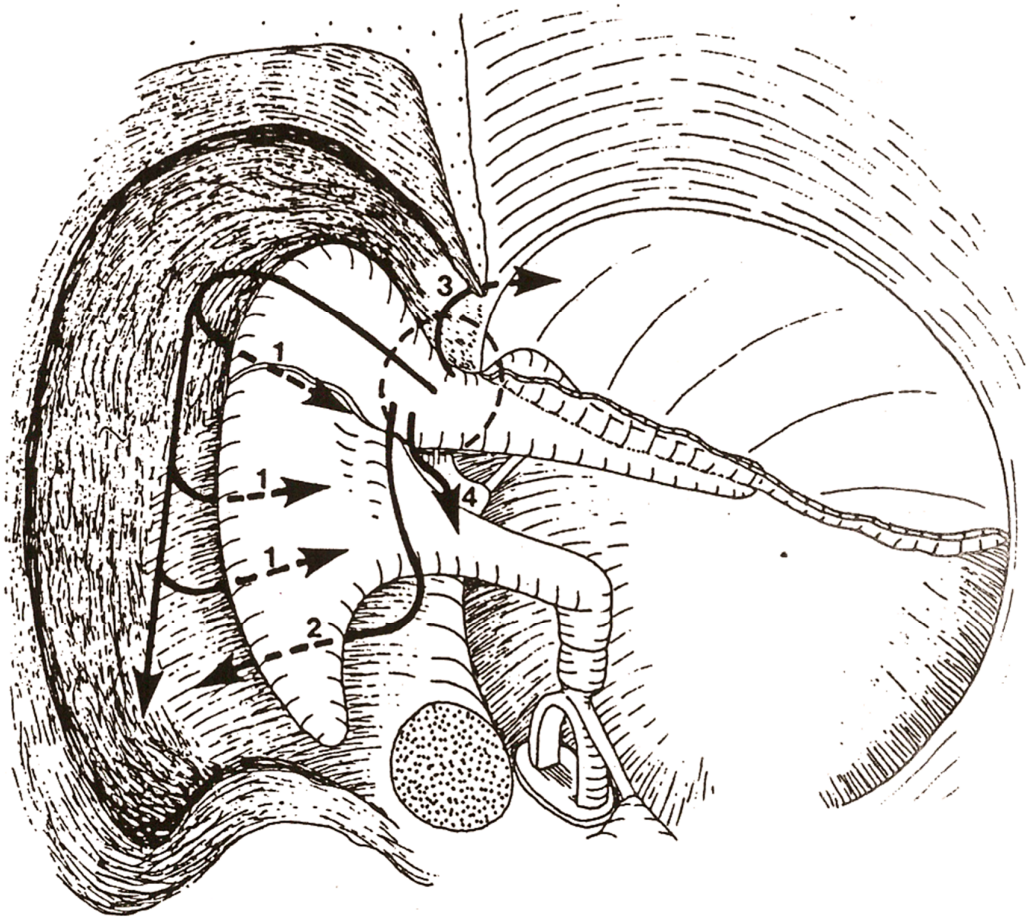
Medial extension:

1. Superior aspect of the malleus head and incus body as a retraction into medial attic
2. From Shrapnell's membrane along the incus body and medial to the short process of the incus continuing into the attic
3. From Shrapnell's membrane and from the Prussak's space under the anterior malleolar fold into the anterior part of the tympanic cavity
4. From Shrapnell's membrane between malleus neck and the long process of the incus into the mesotympanum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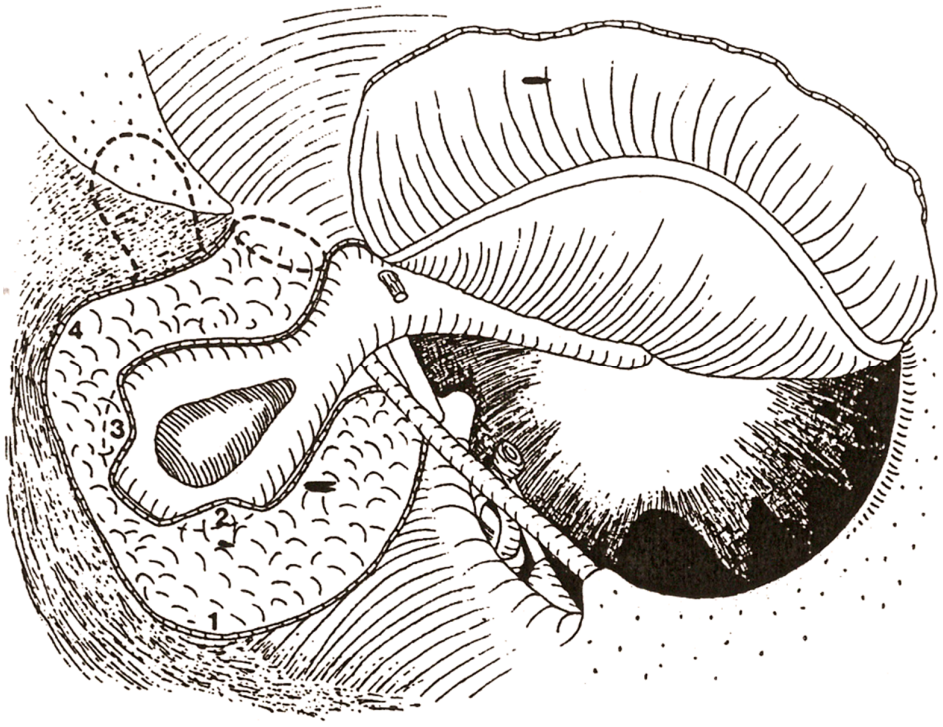
Anterior extension:

From Shrapnell's membrane along the lateral and superior attic medially to the malleus head and from there possibely to epitympanic sinus



Sinus Cholesteatoma:

The anterior wall of the cholesteatoma memebrane emerges as retraction from the atropic drum along the malleus handle. It is attached

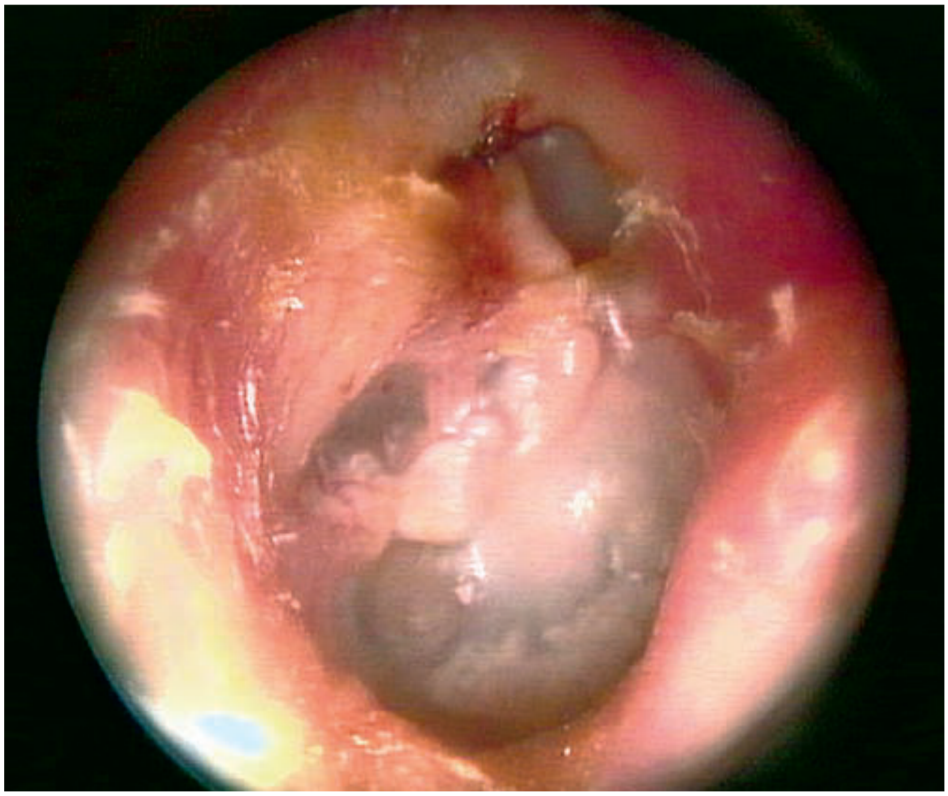
1. To the posterior aspect of promontary
2. To the styloid eminence inferiorly to the lateral tympanic sinus posteriorly and to the facial sinus
3. The pyramidal eminence.

Medially it covers the round window niche the sinus tympani and the footplate region. Superiorly it covers the defective incus which is partly resorbed and the eminence of the horizontal part of the facial nerve

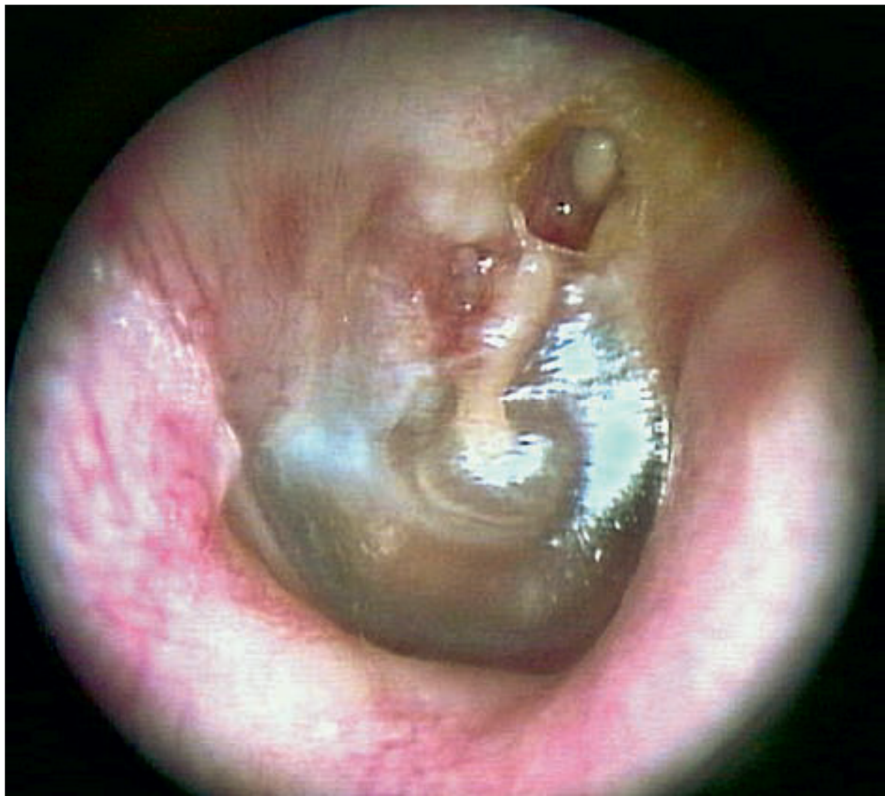
It may extend under the incus body to the tympanic isthmus

Tensa retraction cholesteatoma:

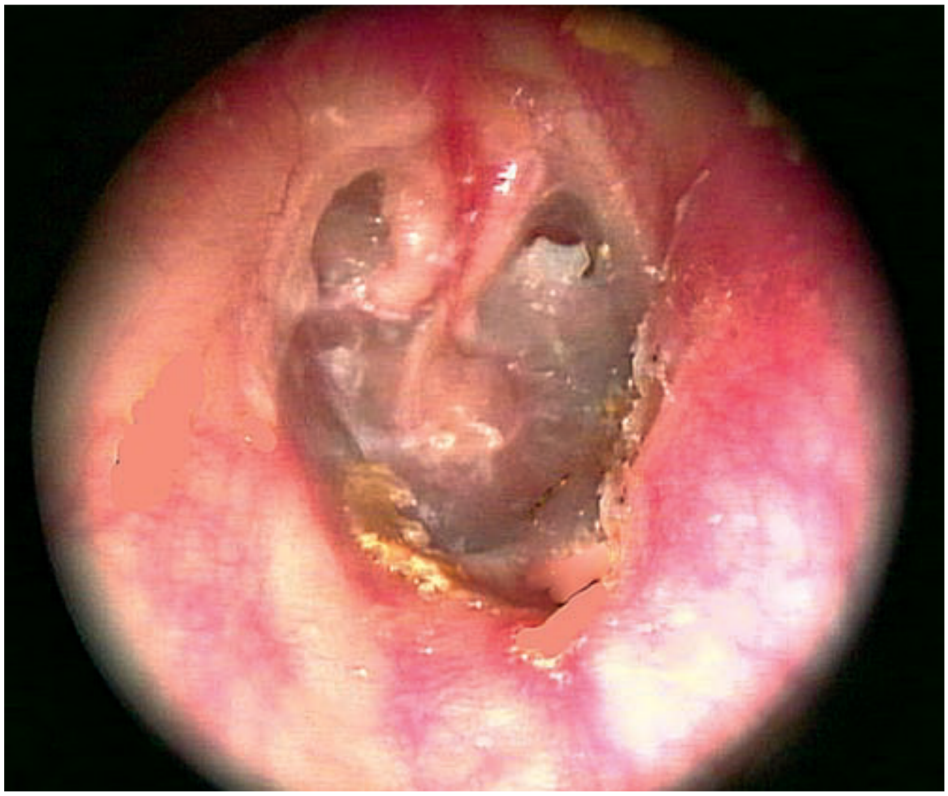
Entire pars tensa is retracted and draped over the walls of the tympanic cavity extending into the tympanic orifice and from there under the anterior malleolar fold towards the attic. The cholesteatoma membrane cover the promontory and th posterior tympanum where it usually causes resorption of the long process of the incus and the stapes crura .It may extend under the anterior malleolar fold to the attic. The malleus handle is often resorbed



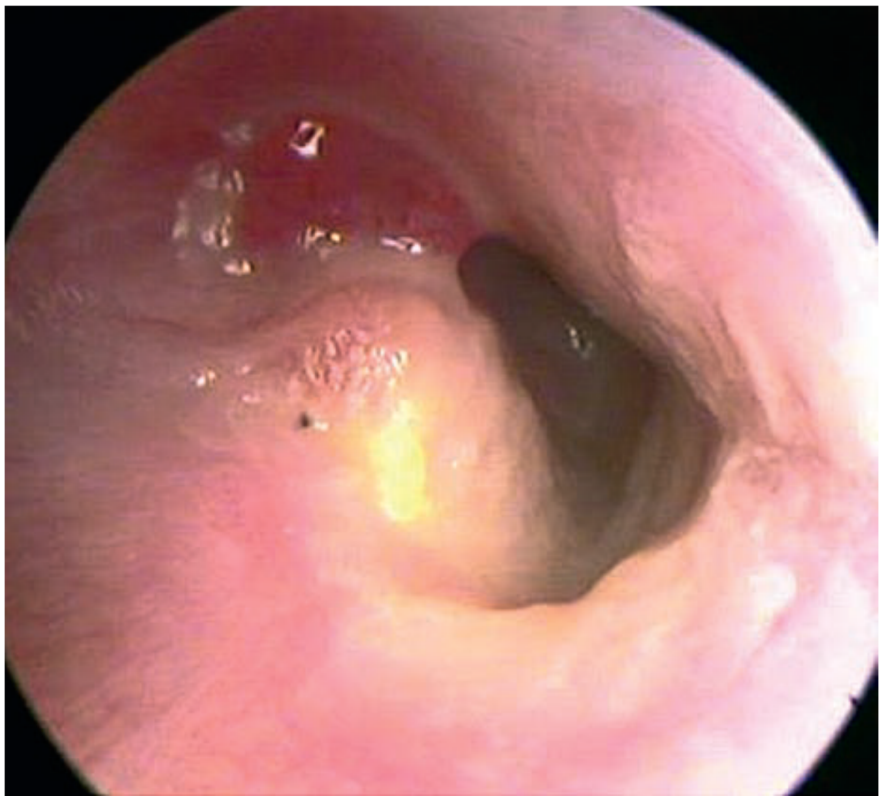
Posterior epitympanic cholesteatomas begin in the pars flaccida and progress posteriorly, medial and lateral to the incus.



Anterior epitympanic cholesteatomas also begin in the pars flaccida but grow anterior to the head of the malleus.

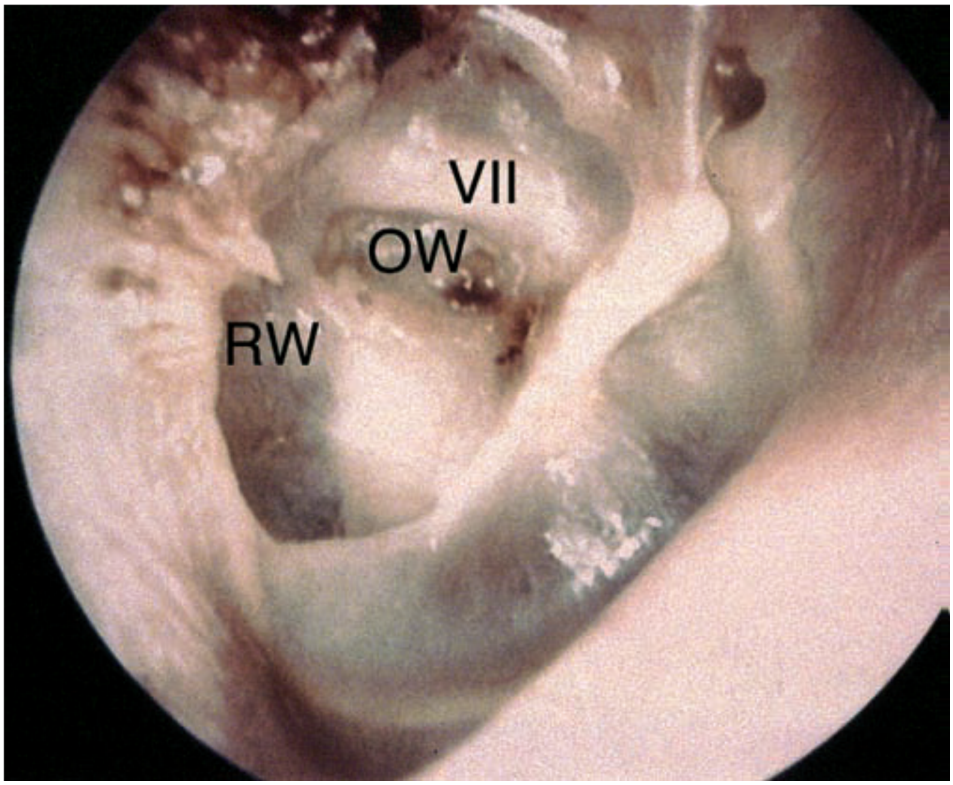


Mesotympanic (middle ear) cholesteatomas begin in the posterior half of the pars tensa and grow medially, along the stapes and into the sinus tympani.



Holotympanic cholesteatomas can begin in the pars fiaccida or pars tensa and grow to fill the middle ear, attic, and mastoid

A cholesteatoma that has eroded the scutum (lateral epitympanic bone) to invade the attic.



A middle ear cholesteatoma that has eaten away the incus and stapes and draped itself onto the facial nerve (VII) and oval (OW) and round windows (RW).

Hidden areas of cholesteatoma :

1. Facial recess
2. Sinus tympani
3. Anterior to the cochleariform process
4. Anterior to the cog in the anterior epitympanum, abutting the semicanal of the tensor tympani.

.

Cholesteatoma occurs in adults and children of any age. Acquired cholesteatomas are far more common than congenital cholesteatomas. Acquired cholesteatomas are usually heralded by ear drainage, sometimes malodorous, and often persistent or recurrent despite treatment with antibiotic drops. Pain does not usually occur. Hearing loss is common but may not be reported by the patient and may go undetected in children. Tinnitus is rare. Vertigo is also uncommon and indicates the presence of labyrinthitis or labyrinthine fistula. Occasionally, the development of a suppurative complication (such as mastoiditis or even meningitis) is the first mode of presentation

The diagnosis of cholesteatoma is by physical examination, with imaging studies playing a confirmatory role. The physical examination should include otoscopy and otomicroscopy, and occasionally otoendoscopy which reveals foul smelling keratin debris. The benefits of microscopy include magnification, illumination (allowing one to see fluid or a sac through a translucent drum), binocular depth perception (useful for evaluating the extent of retraction pockets), and the ability to debride, suction, and probe. Under the microscope, the examiner can elevate crusts and suction away any pus or secretions. It is particularly important to inspect the attic, where cholesteatomas most commonly arise. Cholesteatoma will appear as a deep retraction pocket with purulent discharge or squamous epithelial debris. If the ear is acutely inflamed, a polyp may be present and careful debridement and cauterization will reveal the retraction pocket, yet to be described here. An attic polyp usually but not always, signifies cholesteatoma; other forms of middle ear inflammation can occasionally cause polyps. A cholesteatoma sac may occasionally occur alongside a tympanic membrane perforation, so it is important to examine the attic even if a central perforation is present

DIAGNOSTIC METHODS:

X RAY MASTOID: Law's view

Anatomical variations like low lying dura forward lying sinus plate can be appreciated

Extent of pneumatisation

Type of mastoid

However, there will be overlapping of EAC with petrous bone which proves the disadvantage of taking xray mastoid alone.

Owen's view - to study the ossicles

CT SCAN:

The main value of CT is for preoperative planning—to determine the *size* of the mastoid cavity, the *extent of disease*, and the presence of potential *complications*. CT provides an anatomical roadmap that can be used at surgery. CT has to be taken in both bony and soft tissue windows. In bony cuts soft tissue cannot be outlined and in soft tissue cuts bony landmarks cannot be outlined.Moreover ,CT cannot able to distinguished between cholesteatoma , cholesterol granuloma ,scar tissue, inflammatory changes and granulation tissue

MRI:

Mainly useful for cholesteatoma with intracranial complications. Cholesteatoma will be shown as a hypodense lesions in T1 weighted images and as a hyperdense lesions in T2 weighted images. It cannot differentiate cholesteatoma from cholesterol granuloma which is the important differential diagnosis for hyperintense lesions in T2 weighted images

Now comes the role of diffusion weighted images which is able differentiate cholesteatoma from cholesterol granuloma. Cholesteatoma shows diffusion restriction due it keratin content which is lacking in cholestrol granuloma and other middle ear cleft masses.

SURGERY FOR CHOLESTEATOMA:

Modified Radical Mastoidectomy or canal wall down mastoidectomy:

Modified Radical Mastoidectomy is performed to eradicate mastoid disease, in which the epitympanum, mastoid antrum, and external auditory canal are converted into a common cavity exteriorized through the external Meatus.

Indications:

(1) Extensive damage by disease to the posterior canal wall

(2) Severely contracted mastoid with low-lying tegmen and far forward sigmoid sinus preventing adequate visualization through a standard canal wall up approach,

(3) Cholesteatoma in an only hearing ear, and

(4) Labyrinthine fistula in an ear with extensive cholesteatoma.

Intact canal wall or canal wall up mastoidectomy :

The canal wall up mastoidectomy preserves the posterior bony canal wall and thereby results in normal ear canal anatomy.

Indications:

1. Cholesteatoma in children and in patients with highly pneumatized mastoids
2. Minor epitympanic erosion
3. Mesotympanic cholesteatoma

Radical mastoidectomy:

Radical mastoidectomy is performed to eradicate middle ear and mastoid disease in which the mastoid antrum, tympanum, and external auditory canal are converted into a common cavity exteriorized through the external meatus. This operation involves removal of the tympanic membrane and ossicular remnants, with the exception of the stapes, and does not involve any reconstructive or grafting procedure. Frequently, the surgeon places a plug of soft tissue in the tubotympanum or may lay soft tissue over the middle ear to assist in healing

Atticotomy

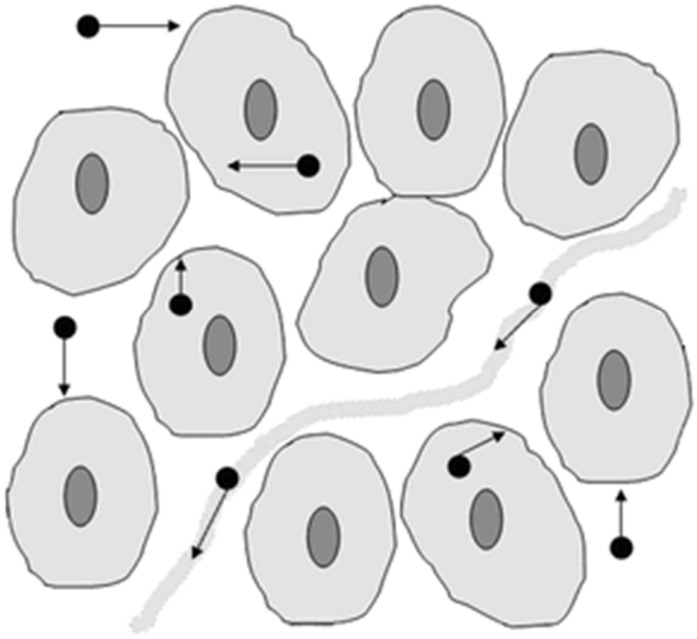
In an atticotomy, only a limited portion of the wall of the EAC is sacrificed. A small attic cholesteatoma is exteriorized by drilling the scutum to the limits of the cholesteatoma sac. The defect is reconstructed with a cartilage graft or autologous bone.

Atticoantrotomy :

Atticoantrotomy is an extension of the atticotomy in a posterior direction through the transmeatal route . The lateral attic and aditus are removed, and the antrum is entered. The posterosuperior bony ear canal wall is removed ,and the access to the antrum is gradually widened

MRI - DIFFUSION WEIGHTED IMAGES

For two decades, diffusion-weighted imaging (DWI) has been applied to the evaluation of intracranial diseases, such as cerebrovascular accidents, trauma, epilepsy, depression, dementia, and neurotoxicity. In the 1990s, a series of technologic advances made it possible to translate DWI measurements to extracranial sites, DWI explores the random motion of water molecules in the body. Water molecules held in a container outside the body are in constant random brownian motion. This uninhibited motion of water molecules is free diffusion. By contrast, the movement of water molecules in biologic tissues is restricted because their motion is modified and limited by interactions with cell membranes and macromolecules



View larger version (68K)

Diffusion of water molecules. Restricted diffusion: cellularity and intact cell membranes. Drawing represents 1 voxel of tissue evaluated by diffusion-weighted imaging (DWI) containing cells and blood vessel. Note water molecules (black circles with arrows) within extracellular space, intracellular space, and intravascular space, all of which contribute to measured MR signal. In this highly cellular environment, water diffusion is restricted because of reduced extracellular space and by cell membranes, which act as barrier to water movement.

In biologic tissue, the DWI signal is derived from the motion of water molecules in the extracellular space, the intracellular space, and the intravascular space water molecules in the intravascular space will have a greater diffusion distance because of blood flow than those in the extracellular and intracellular spaces. Clearly, the contribution of intravascular water diffusion to the measured DWI signal can vary among tissues. In tumors showing increased vascularity, the contribution of intravascular water diffusion to the MR signal may account for a significant proportion

The degree of restriction to water diffusion in biologic tissue is inversely correlated to the tissue cellularity and the integrity of cell membranes The motion of water molecules is more restricted in tissues with a high cellular density associated with numerous intact cell membranes (e.g., tumor tissue). The lipophilic cell membranes act as barriers to motion of water molecules in both the extracellular and intracellular spaces. By contrast, in areas of low cellularity or where the cellular membrane has been breached, the motion of water molecules is less restricted.

A less cellular environment provides a larger extracellular space for diffusion of water molecules, and these molecules may also freely transgress defective cell membranes to move from the extracellular into the intracellular compartments

DWI technique in cholesteatoma imaging

EPI DWI technique: Routinely used in brain imaging, EPI DWI is limited in the skull base, among other locations, by susceptibility artifacts apppearing at air-bone interfaces. On the other hand, high spatial resolution is required for detection of small lesions in the middle ear cavity.

High sensitivity of EPI DWI in detection of middle ear cholesteatoma has been reported in series that included lesions larger than 5 mm. However, in cases of smaller lesions, sensitivity becomes very low due to prominent artifacts obscuring the lesion and to low spatial resolution. When only EPI DWI is used, the addition of DPI adds sensitivity for detection of lesions smaller than 5 mm and should be routinely employed.

NON EPI DWI technique: During the past decade, fast spin-echo–based non-EPI DWI techniques have been developed by different MR imaging vendors. These techniques include single-shot turbo spin-echo DWI, half-Fourier acquisition single-shot turbo spin-echo (HASTE) DWI (Siemens Medical Solutions, Erlangen, Germany), PROPELLER DWI, BLADE DWI (Siemens Medical Solutions), and multishot DWI turbo spin echo. These sequences minimize most susceptibility artifacts and allow thinner sections and higher imaging matrices, yielding sensitivities in the 90%–100% range for lesions as small as 2 mm. In comparison with EPI DWI, these non-EPI DWI techniques improve sensitivity for detection of lesions smaller than 5 mm and allow better lesion delineation. Both EPI and non-EPI DWI techniques are highly specific for cholesteatoma

DWI of cholesteatoma an imaging criteria and pitfalls:

The main diagnostic criterion for cholesteatoma at DWI is lesion hyperintensity, compared with the signal intensity of brain, on b = 0 sec/mm2 images that persists or increases on high b value (800–1000 sec/mm2) images

False-Negative Findings: False-negative findings at non-EPI DWI of middle ear cholesteatomas are mostly due to failure of the technique to demonstrate mural cholesteatomas and lesions smaller than 2–3 mm. Both of these factors are responsible for sensitivity values below 90%

Mural cholesteatomas are a frequent cause of false-negative results at both DWI and DPI. Cholesteatomas may lose their keratin content because of spontaneous automastoidectomy, leaving an empty retraction pocket . However, the remaining epithelium covering the cavity retains its aggressive potential, and the lesion is clinically considered a cholesteatoma (mural or evacuated cholesteatoma). In these cases, since no keratin content persists, DWI results may be falsely negative.

False-Positive Findings:

On high b value diffusion-weighted images, hyperintensity that does not correspond to a cholesteatoma has been described in the following situations: after recent surgery due to residual hemorrhage, in ears containing Silastic sheets (Dow Corning) or bone pâté , cerumen located in the EAC , cholesterol granuloma , artifacts due to metallic dental braces , and in cases of middle ear or mastoid abscess . In practical terms, the specificity of the technique approaches 100%, since most causes of false-positive results can be inferred from the patient's clinical history or from knowledge of the type of surgery performed and the materials employed Cholesterol granulomas occasionally show some hyperintensity at high b value DWI, but it is usually lower than that found in cholesteatoma

Aims of the Study

AIMS OF THE STUDY

1. To differentiate cholesteatoma from other masses in middle ear cleft

2. To find out the extent of lesion preoperatively amd compare with peroperative findings and to plan for surgical procedures

3. To find out any recurrent and residual disease

Minor Objectives

1. Condition of the mastoid
2. Associated secretory otitis media

Materials

MATERIALS

STUDY PLACE :

Rajiv Gandhi Government General Hospital, Chennai – 600003.

COLLABORATING DEPARTMENT:

Upgraded Institute of Otorhinolaryngology

STUDY DESIGN **:** Retrospective and Prospective study

STUDY PERIOD **: NOVEMBER 2013 TO NOVEMBER 2015**

STUDY POPULATION:

All patients with cholesteatoma who are reported to the upgraded institute of otorhinolaryngology during the study period with the fulfillment of inclusion criteria.

INCLUSION CRITERIA :

1 .Age 13yrs and above

2. Both sexes (male and female)

3. Newly diagnosed cases

4. Recurrent cases

5. Aural polyp

6. Aural granulation

7. Attic retraction

8. severe retraction in posterior superior quadrant

EXCLUSION CRITERIA :

1. Age below 13

2. Impending subperiosteal abscess

3. Mastoid fistula

4 .Intracranial complications

INVESTIGATION:

1. ENT examination and otoscopy findings
2. XRAY MASTOID
3. PTA
4. HRCT
5. MRI-DWI

DATA COLLECTION: Clinical

BENEFIT TO THE COMMUNITY :

1. Complete disease clearance
2. Reduced morbidity

CONFLICT OF INTEREST : NIL

FINANCIAL SUPPORT : NIL

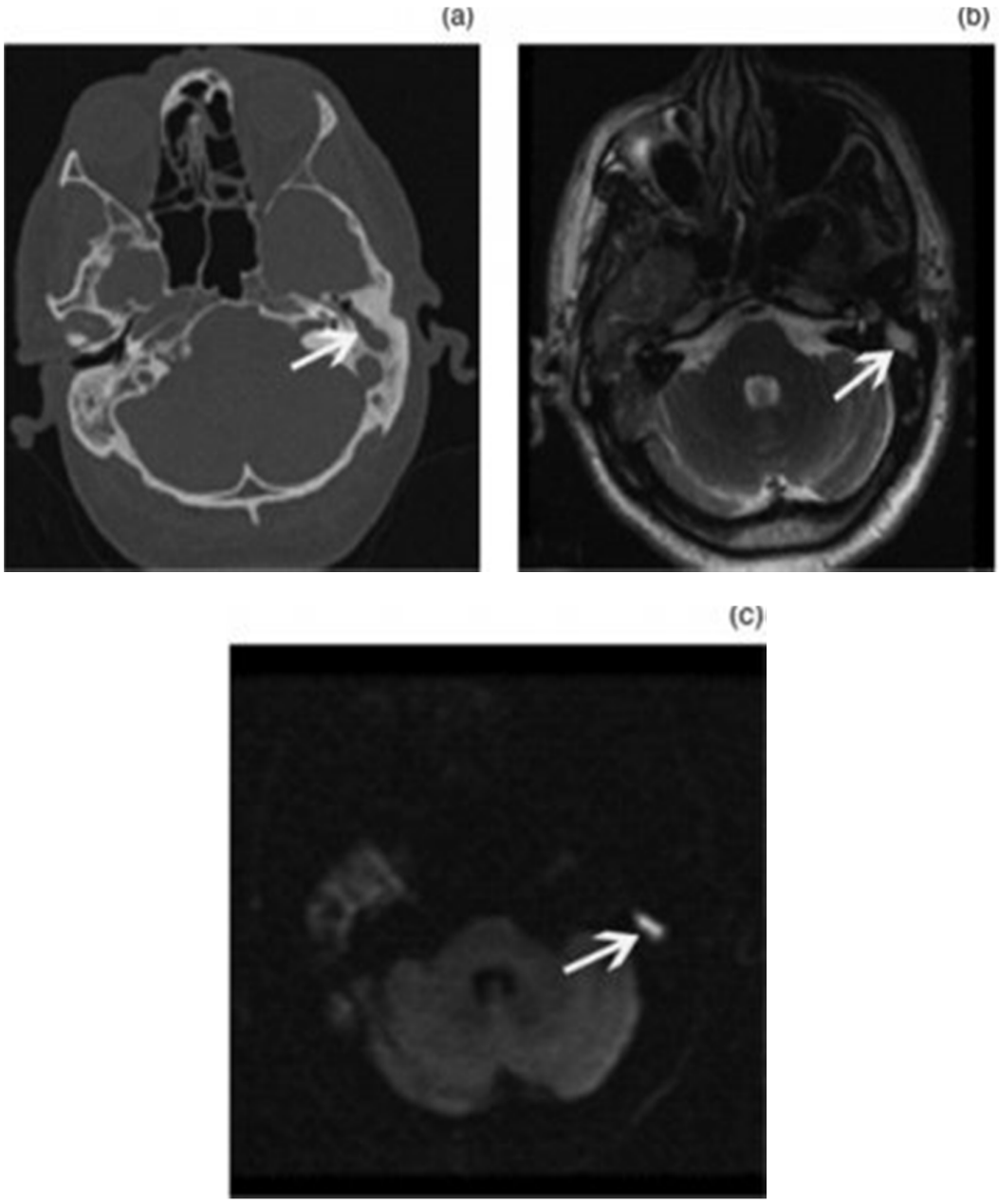
ETHICAL COMMITTEE APPROVAL:

Institutional Ethical Committee, Government General Hospital Madras Medical College, Chennai reviewed the experimental design and protocol as well as the letter of information and consent form. Full approval of the broad was granted . All patients were given information outlining the experimental protocol and all patients signed a consent form prior to entering the study

Methodology

METHODOLOGY

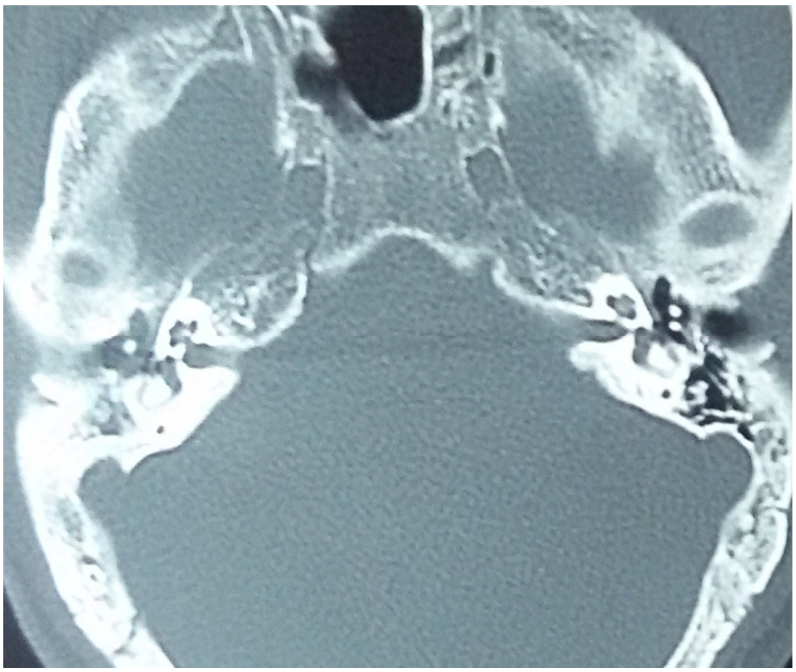
This is a prospective study conducted in our institution from November 2013 to September 2015. All patients who attend our op with complaints of chronic ear discharge are included in the study. After clinical examination including otoscopy and routine blood investigations HRCT and MRI DWI are taken. Then patients are subjected to surgery .preoperative radiological and peroperative findings are correlated



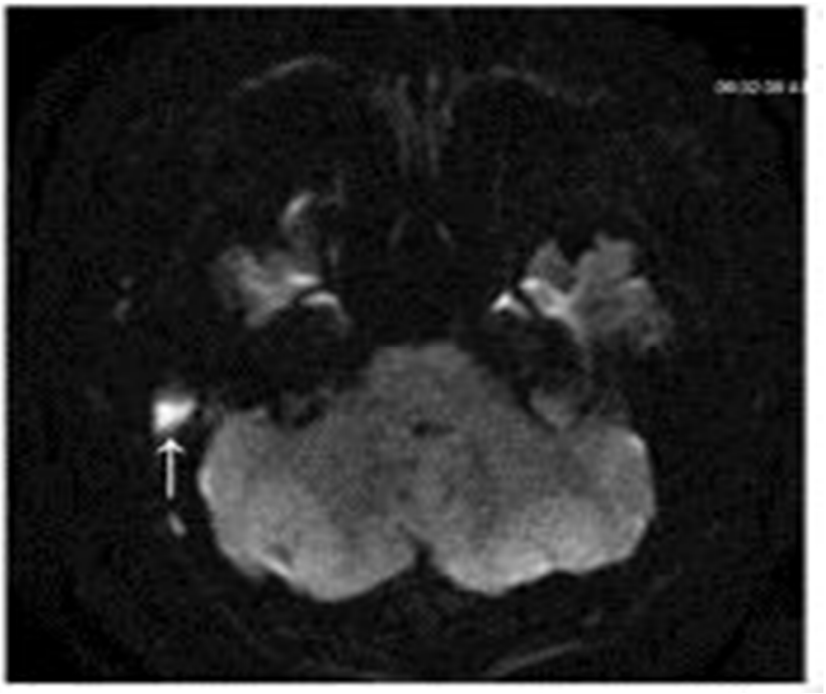
a) Soft tissue mass in middle ear in HRCT

b) Hyperintense lesions in T2 images

c) Diffusion restriction



HRCT of a patient with posterior superior retraction pocket



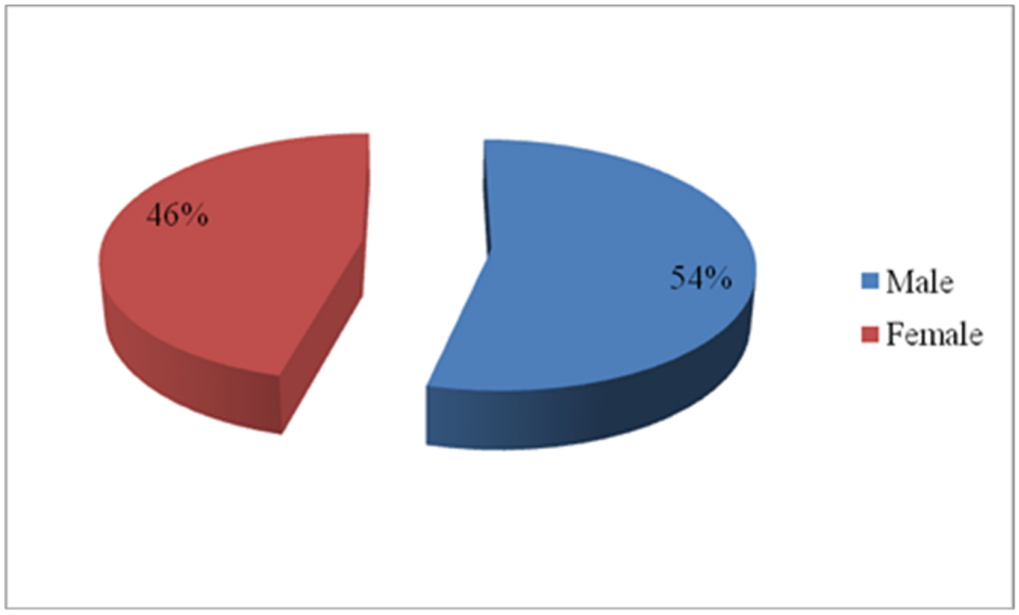
DWI image of the same patient showing diffusion restriction

Statistics

STATISTICS

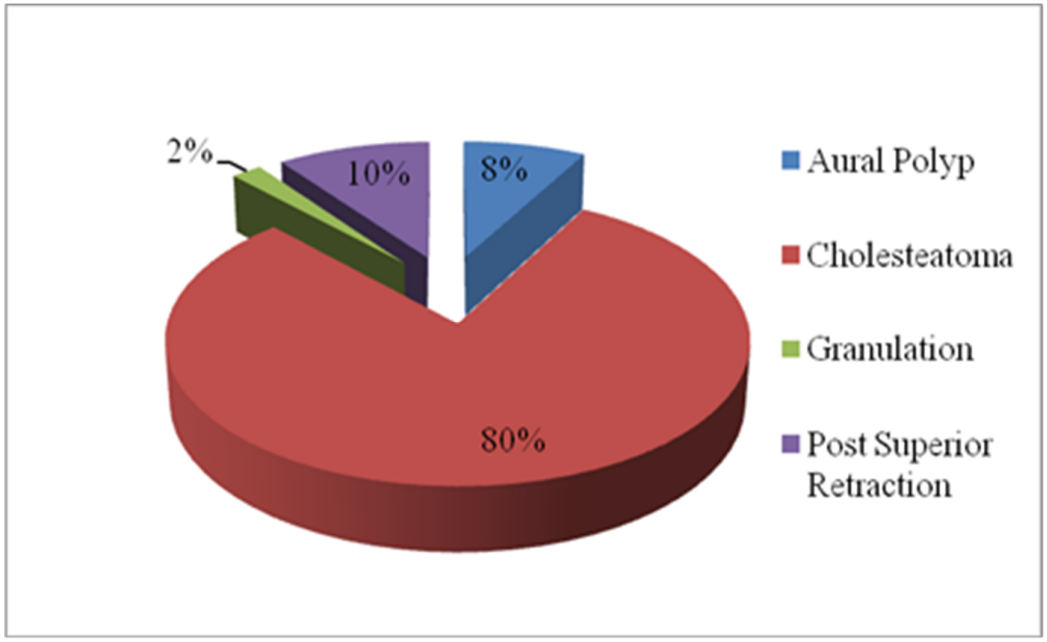
AGE		
N		50
Mean		27.68
Median		26.00
Mode		45
Std. Deviation		10.693
Minimum		14
Maximum		55

		Count	Column N %
Sex	Male	27	54.0%
	Female	23	46.0%
	Total	50	100.0%



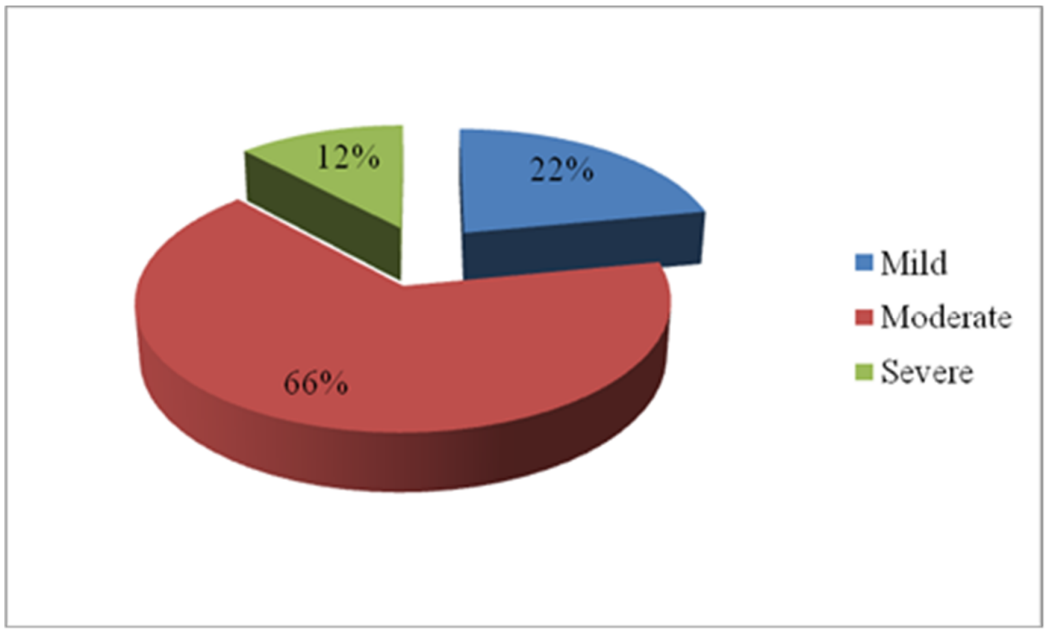
Duration of disease	
N	50
Mean	2.50
Median	2.00
Mode	2
Std. Deviation	1.555
Minimum	1
Maximum	5

		Count	Column N %
Diagnosis	Aural Polyp	4	8.0%
	Cholesteatoma	40	80.0%
	Granulation	1	2.0%
	PSRP	5	10.0%
	Total	50	100.0%

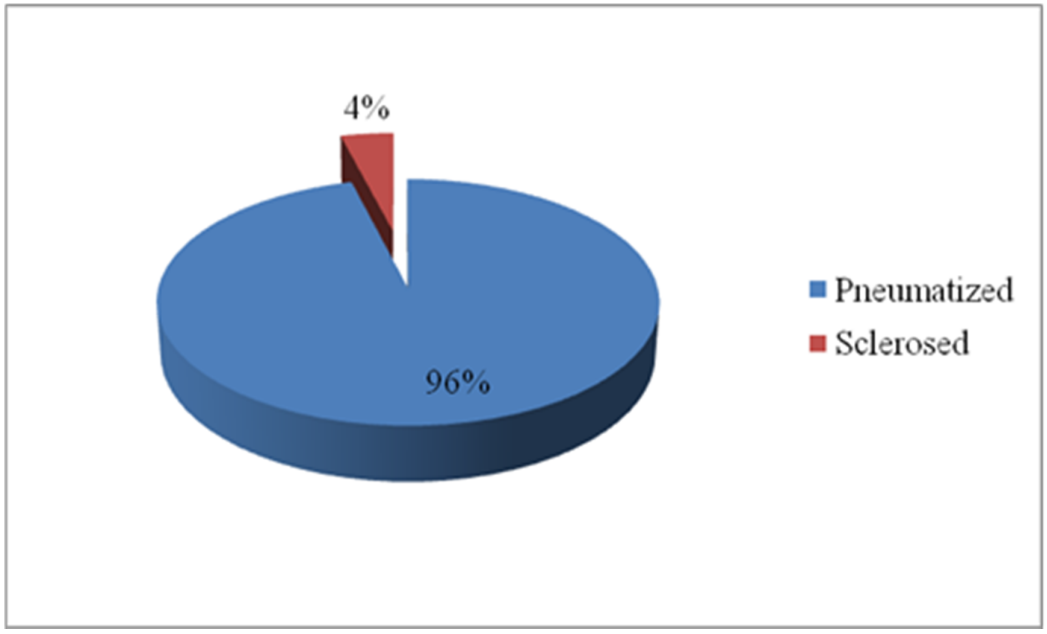


Severity of hearing loss

		Count	Column N %
Severity of hearing loss	Mild	11	22.0%
	Moderate	33	66.0%
	Severe	6	12.0%
	Total	50	100.0%

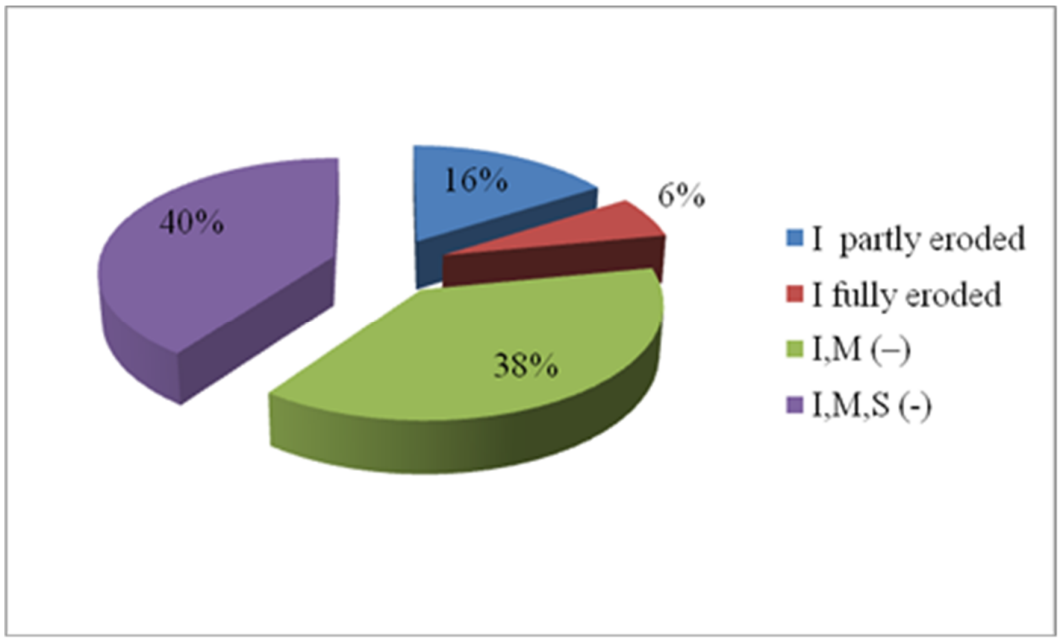


		Count	Column N %
Pneumatisation of mastoid	Pneumatized	48	96.0%
	Sclerosed	2	4.0%
	Total	50	100.0%

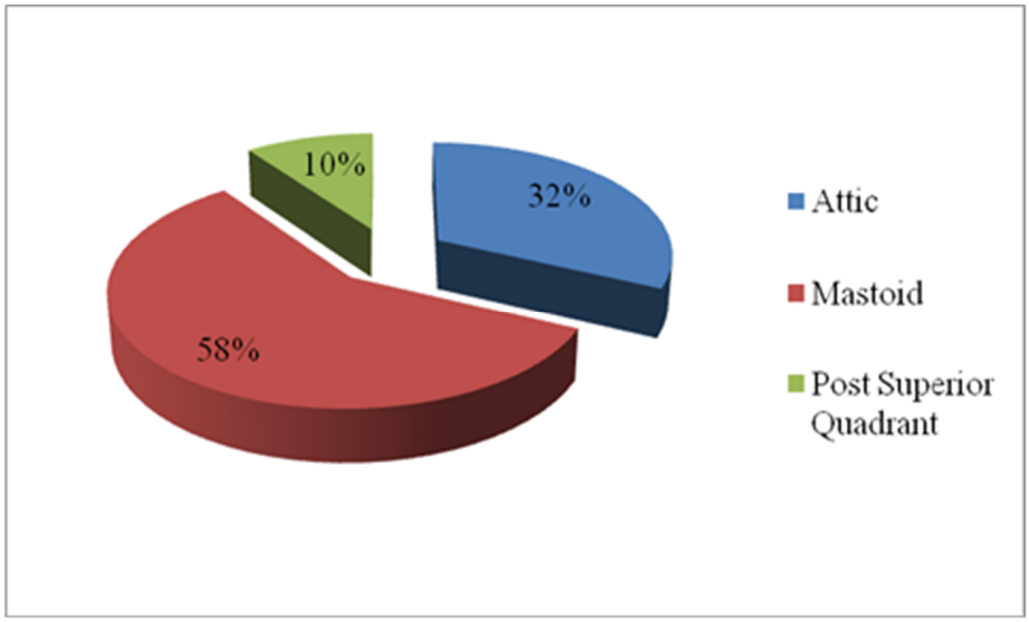


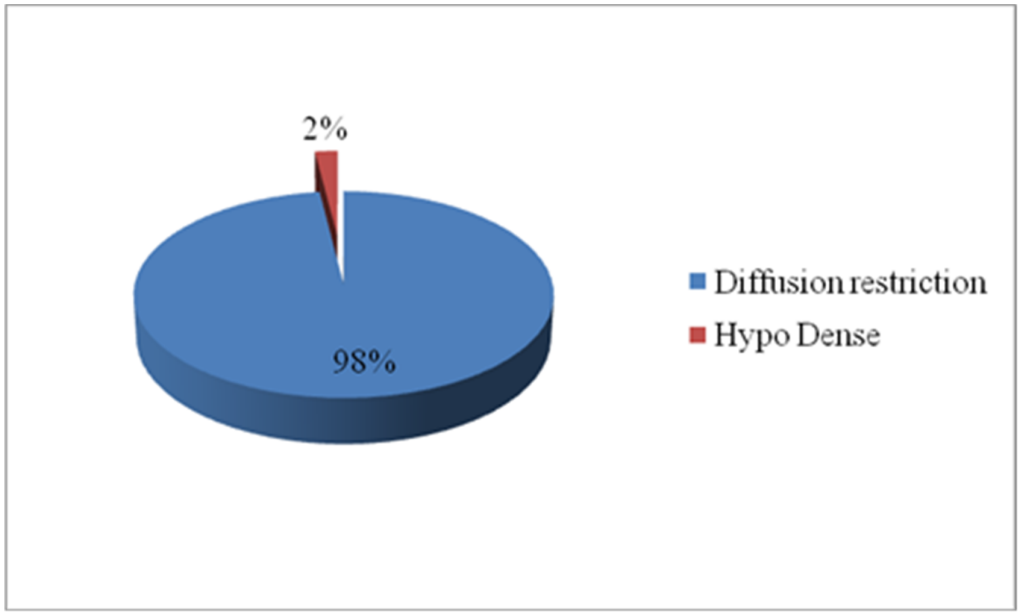
Radiological ossicular status

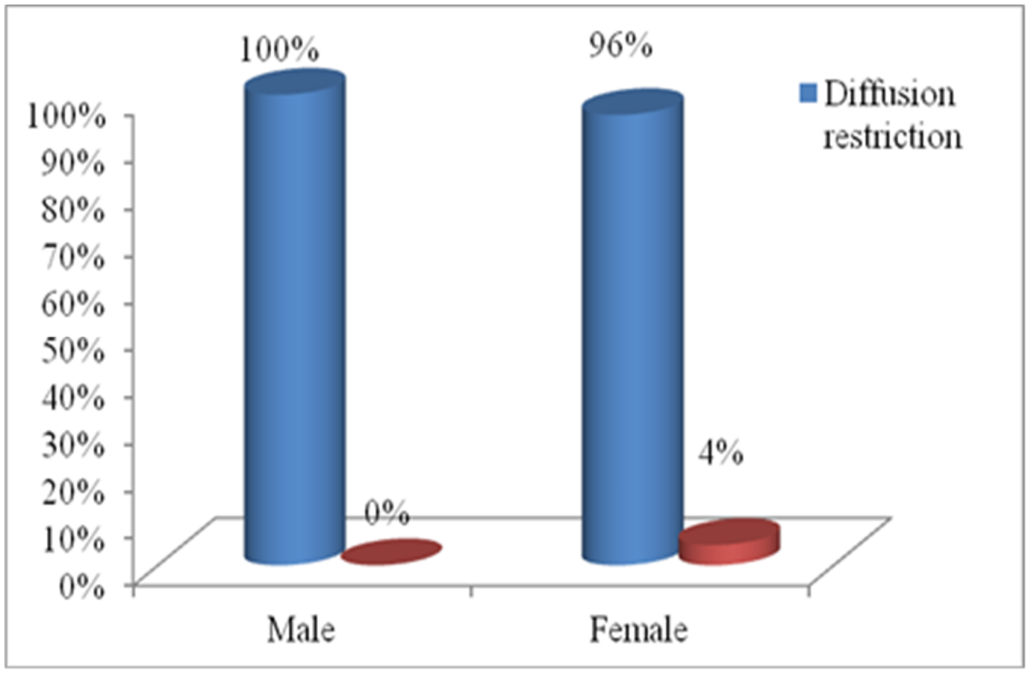
Ossicular Status	Incus partly eroded	8	16.0%
	Incus fully eroded	3	6.0%
	Incus,Malleus eroded	19	38.0%
	Incus,Malleus,Stapes eroded	20	40.0%
	Total	50	100.0%

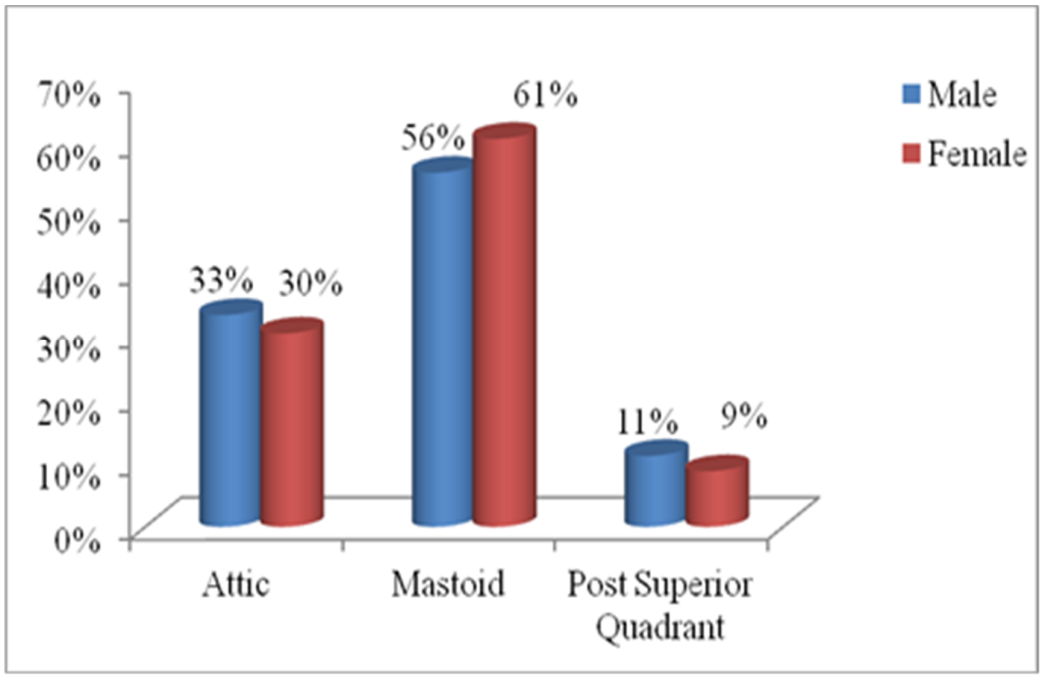


		Male		Female	
		Count	**Column N %**	**Count**	**Column N %**
HRCT	Soft Tissue Mass	27	100.0%	23	100.0%
	Total	27	100.0%	23	100.0%
T1	Hypo Dense	27	100.0%	23	100.0%
	Total	27	100.0%	23	100.0%
T2	Hyper Intense	27	100.0%	23	100.0%
	Total	27	100.0%	23	100.0%
DWI	Diffusion restriction	27	100.0%	22	95.7%
	Hypo Dense	0	.0%	1	4.3%
	Total	27	100.0%	23	100.0%
E	Attic	9	33.3%	7	30.4%
	Mastoid	15	55.6%	14	60.9%
	Post Superior Quadrant	3	11.1%	2	8.7%


10%
32%
58%
Attic
Mastoid
Post Superior Quadrant

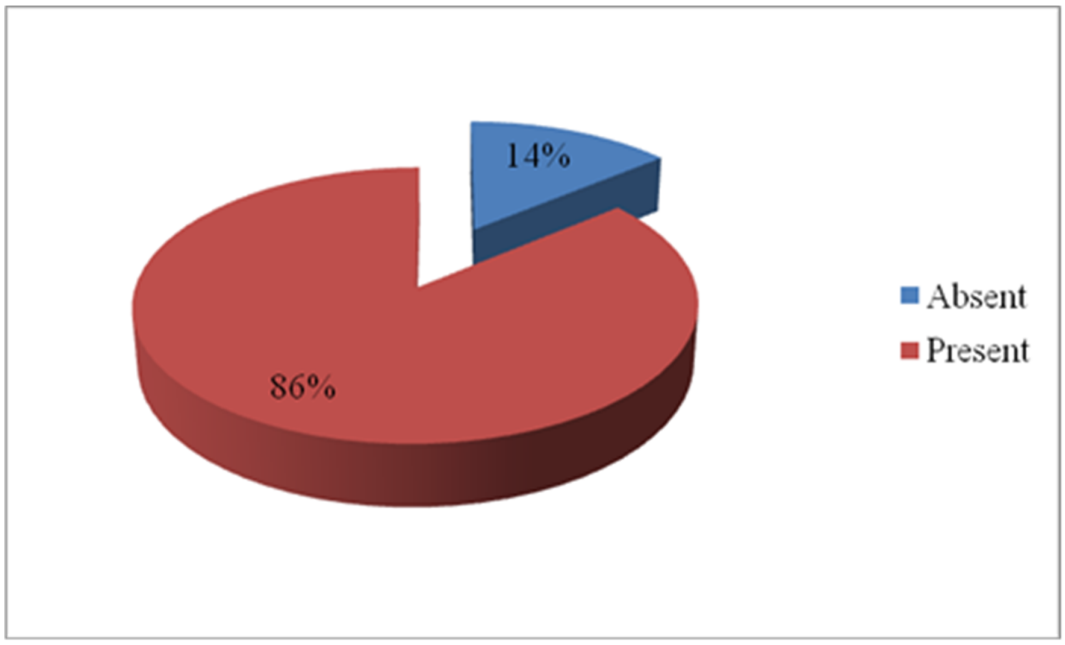

2%
98%
Diffusion restriction
Hypo Dense


100%
96%
Diffusion restriction
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
0%
4%
Male
Female


70%
60%
50%
40%
30%
20%
10%
0%
33%
30%
56%
61%
11%
9%
Male
Female
Attic
Mastoid
Post Superior Quadrant

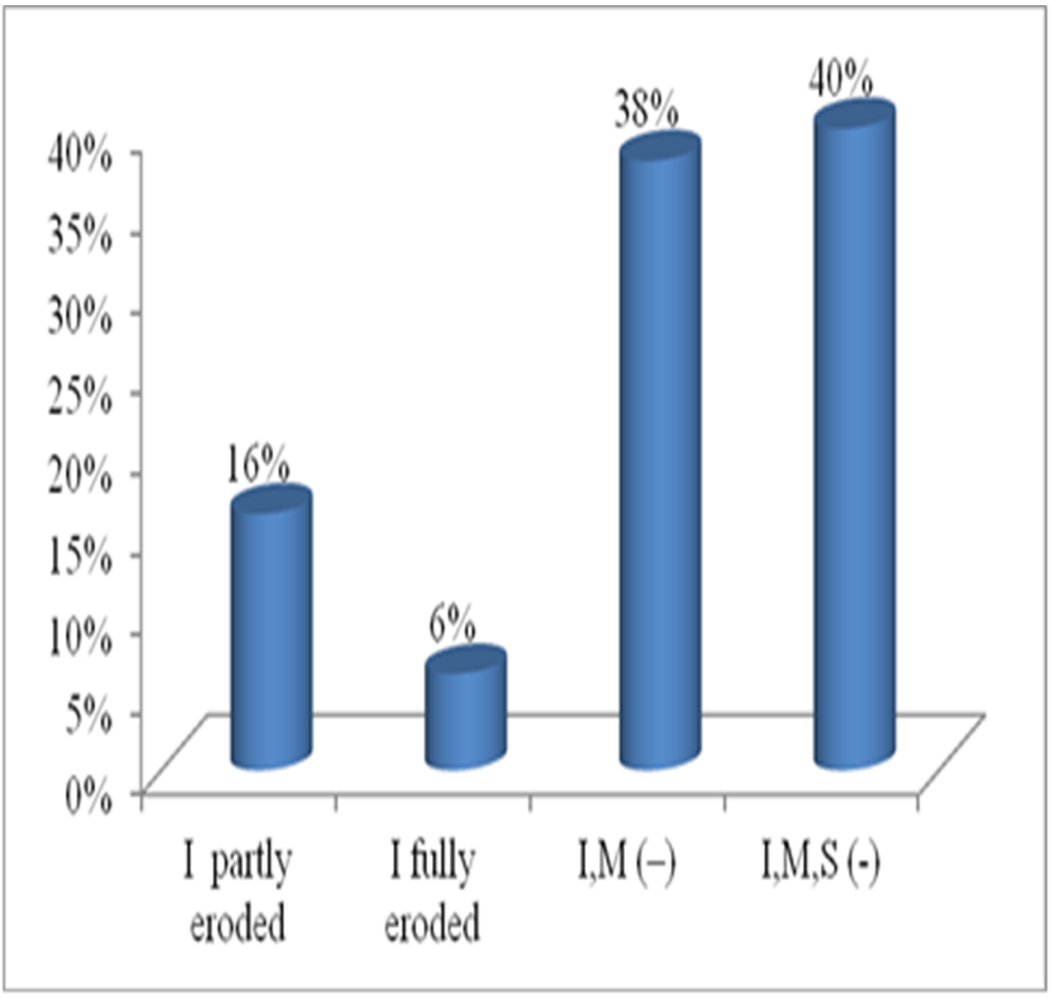
Intraoperative findings

		Count	Column N %
Cholesteatoma	Absent	7	14.0%
	Present	43	86.0%
	Total	50	100.0%
Extension	Same	50	100.0%
	Total	50	100.0%



Intraoperative ossicular status

		Count	Column N %
Ossicular status	Incus partly eroded	8	16.0%
	Incus fully eroded	3	6.0%
	Incus,Malleus eroded	19	38.0%
	Incus,Malleus,Stapes eroded	20	40.0%
	Total	50	100.0%
Mucosal status	Unhealthy	50	100.0%
	Total	50	100.0%


40%
35%
30%
25%
20%
15%
10%
5%
0%
16%
6%
38%
40%
I partly eroded
I fully eroded
I,M (–)
I,M,S (-)

DWI * sex

	P value
Fisher's Exact Test	.460

E * sex

	Value	df	P value
Pearson Chi-Square	.166	2	.921

	Intraop Positive	Intra op Negative	Total
MRI Positive	43	6	49
MRI Negative	0	1	1
Total	43	7	50

Parameter	Estimate	Lower - Upper 95% CIs
Sensitivity	100%	(91.8, 100)
Specificity	14.29%	(2.568, 51.31)
Positive Predictive Value	87.76%	(75.76, 94.27)
Negative Predictive Value	100%	(20.65, 100)
Diagnostic Accuracy	88%	(76.19, 94.38)
Cohen's kappa	0.2228	(0.04838 - 0.3972)

Review in Literature

REVIEW IN LITERATURE

	Patient number	**Sensitivity**	**Specificity**	**PPV**	**NPV**	**Minimum detected Cholesteatoma (mm)**
Dhepnorrarat et al. 2008 (8)	**22**	**100**	**100**	**100**	**100**	**3**
De Foer et al. 2008 (11)	**19**	**90**	**100**	**100**	**96**	**2.5**
Plouin–Gaudon et al. 2010 (9)	**21**	**62**	**88**	**89**	**58**	**4**
Khemani et al. 2010 (10)	**38**	**82**	**90**	**96**	**64**	**3**
Rajan et al. 2010 (22)	**15**	**100**	**100**	**100**	**100**	**3**
De Foer et al. 2010 (23)	**120**	**83**	**87**	**96**	**57**	**-**
Pizzini et al. 2010 (24)	**27**	**100**	**100**	**100**	**100**	**2**

In 2010 Schwartz et al performed a study for 12 patients who had undergone DWI for evaluation of a mass in the middle ear, mastoid, or petrous apex. Ten of these patients had previously undergone middle ear surgery, 8 for cholesteatoma resection. On DWI, 9 patients demonstrated restricted diffusion. Of these, 8 patients underwent surgical resection, and all were found to have had a cholesteatoma. Of the 3 patients who had not demonstrated restricted diffusion on DWI, 2 did not undergo surgery and the other was found to have only chronic inflammation at surgery.

In 2010 Ganaha et al performed DWI on 73 patients suspected of having middle ear cholesteatoma, including 21 revision cases. Of 73 subjects, 59 had cholesteatoma that consisted of 41 primary acquired cholesteatoma, 13 had residual and/or recurrent cholesteatoma, four had congenital cholesteatoma, and one had iatrogenic cholesteatoma. Positive DWI findings were observed in 42 subjects and negative findings in 31 subjects. The sensitivity, specificity, and positive and negative predictive values of DWI for cholesteatoma were 69.4%, 92.8%, 97.5%, and 41.9%, respectively.

In the case of 34 patients who were positive for cholesteatoma on both otoscopic and CT examinations, 33 were diagnosed with cholesteatoma. Of the remaining 39 subjects with one or both negative results for cholesteatoma, the sensitivity, specificity, positive predictive value, and negative predictive value of DWI were 57.6%, 92.3%, 93.7%, and 52.1%, respectively.

Cholesteatoma mass diameters were less than 5 mm in 10 out of 18 subjects with both cholesteatoma and negative DWI findings. Of the 21 subjects who received revision surgery, the sensitivity, specificity, and positive and negative predictive values of DWI for residual or recurrent acquired cholesteatoma were 71.4%, 100%, 100%, and 63.6%, respectively.

.In 2012 Ilica et al successfully detecred 11 primary and 5 recurrent lesions out of 17 cholesteatoma cases. Sensitivity 94.1. One primary cholesteatoma with a diameter of 4–5 mm was missed. MRI of patients without cholesteatoma were correctly interpreted as negative for cholesteatoma (specificity, 100%). The positive and negative predictive values for the diffusion-weighted MRI in detecting cholesteatoma were 100% and 80%, respectively.

In 2014 A F Abdel Ghany conducted a study on : 13 patients who performed mastoidectomy for previous cholesteatoma that now presented with clinical and CT signs of recurrence were referred to perform non contrast MRI using T2 and DWI sequences in order to differentiate recurrent cholesteatoma from infected postoperative granulation tissue. : 8 patients showed MRI evidence of recurrent cholesteatoma, findings were confirmed intra-operatively

Discussion

DISCUSSION

The main purpose of this study is to prove the usefulness of MRI DWI in diagnosing cholesteatoma . In this study 50 patients are selected who comes into the inclusion criteria.

Of the 50 patients 40 patients had cholesteatoma clinically, in MRI and also intraoperatively. 4 patients presented as aural polyp clinically. MRI for those patients showed diffusion restriction. Out of this 4, 3 had cholesteatoma intraoperatively 1 patient had only granulation tissue.

5 patients had posterior superior retraction pocket. MRI of those patients showed diffusion restriction but intraoperatively they had only posterior superior retraction pocket.

1 patient presented as granulation tissue, in MRI DWI showed hypodense lesions and intraoperative findings also proved to be only granulation tissue

The sensitivity, specificity, PPV and NPV are 100%, 14.29% , 87.76%, 100% respectively. The diagnostic accuracy of this study is 88%

The 5 patients who presented as posterior superior retraction pocket showed diffusion restriction .but their intraoperative finding doesn't correlate with radiological finding this is due to the fact that posterior superior retraction pocket is nothing but a very early cholesteatoma that is a wide mouthed sac which is a self- cleaning cavity This explains the diffusion restriction

One patient showed false positive result in DWI sometimes cholesterol granuloma show diffusion restriction. But the histopathology of this patient showed only granulation tissue.

In most of the studies conducted on DWI for cholesteatoma the sensitivity is 100% which is also proved to be the same in this study. The specificity is 100% but in this study it turned out to be only 14.29%. The PPV and NPV is almost similar when compared to other study.

Conclusion

CONCLUSION

Preoperative imaging with MRI DWI is an imprtant evaluation to differentiate cholesteatoma from scar tissue, granulation tissue and inflammatory changes particularly when CT findings are equivocal It can also used for the detection of recurrent and residual cholesteatoma and to know the extent of the lesion so that the surgeon can plan the surgery.It is fast , convenient and very robust.With high sensitivity, specificity ,PPV and NPV it can spare the patient from surgical morbidity.

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Annexures

PROFORMA

CASE NUMBER :

NAME :

AGE / SEX :

IP NO. :

DATE OF ADMISSION :

DATE OF DISCHARGE:

OCCUPATION :

INCOME :

ADDRESS :

COMPLAINTS OF :

1. EAR DISCHARGE
2. HARD OF HEARING
3. EAR PAIN
4. RINGING SENSATION
5. FEVER
6. VERTIGO
7. HISTORY OF TRAUMA
8. SYMPTOMS OF INTRACRANIAL COMPLICATIONS
    a. HEADACHE
    b. VOMITING
    c. SEIZURE

PAST HISTORY

HISTORY OF PREVIOUS EAR SURGERY

FAMILY HISTORY

PERSONAL HISTORY

EXAMINATION

EAR

PREAURICULAR REGION

PINNA

POST AURICULAR REGION

EXTERNAL AUDITORY CANAL

TYMPANIC MEMBRANE

MASTOID TENDERNESS

THREE FINGER TEST

FACIAL NERVE

TUNING FORK TEST

RINNE

WEBER

ABSOLUTE BONE CONDUCTION TEST

FISTULA TEST

VESTIBULAR SYSTEM

NOSE

THROAT

DIAGNOSIS

PLAN

INVESTIGATIONS

COMPLETE HEMOGRAM
RENAL FUNCTION TESTS
CHEST X RAY
SEROLOGICAL TESTS
ECG
PURE TONE AUDIOGRAM
X RAY MASTOIDS – LATERAL OBLIQUE VIEW.
HRCT TEMPORAL BONE
MRI T1 T2 DWI

MASTER CHART

S. No.	Name	Age	Sex	Clinical Diagnosis	Duration of Disease	Preoperative radiological Findings							Intraoperative findings			
						Pneumatisation of mastoid	Ossicular status	HRCT	T1	T2	DWI	E	C	E	Ossicular status	Mucosal status
1	Deenadayalan	40	M	C (L)	2 yrs	Pneumatized	I,M (–)	STM	HD	HI	DR	M	P	S	S	Unhealthy
2	Dharmalingam	38	M	C (R)	2yrs	Pneumatized	I,M (–)	STM	HD	HI	DR	M	P	S	S	Unhealthy
3	Saroja	45	F	GR (L)	5yrs	Pneumatized	I,M,S (-)	STM	HD	HI	HD	A	A	S	S	Unhealthy
4	Kalaivani	19	F	C (L)	5yrs	sclerosed	I,M,S (-)	STM	HD	HI	DR	M	P	S	S	Unhealthy
5	Vanaroja	24	F	C (R)	1yr	Pneumatized	I,M (–)	STM	HD	HI	DR	M	P	S	S	Unhealthy
6	Panchamurthy	30	M	PSRP (R)	1yr	Pneumatized	I partly eroded	STM	HD	HI	DR	PSQ	A	S	S	Unhealthy
7	Sudhakar	23	M	C (R)	5yrs	Pneumatized	I,M,S (-)	STM	HD	HI	DR	A	P	S	S	Unhealthy
8	Venkatraman	14	M	C (R)	2yrs	Pneumatized	I,M (–)	STM	HD	HI	DR	M	P	S	S	Unhealthy
9	Vishal	14	M	C (L)	1yr	Pneumatized	I,M (–)	STM	HD	HI	DR	M	P	S	S	Unhealthy
10	Rajiv	20	M	C (R)	2yrs	Pneumatized	I,M,S (-)	STM	HD	HI	DR	M	P	S	S	Unhealthy
11	Bhaskar	34	M	AP (L)	1yr	Pneumatized	I,M,S (-)	STM	HD	HI	DR	M	A	S	S	Unhealthy
12	Maheswari	27	F	C (L)	2yrs	Pneumatized	I,M,S (-)	STM	HD	HI	DR	M	P	S	S	Unhealthy
13	Geethanjali	15	F	C (R)	5yrs	Pneumatized	I,M,S (-)	STM	HD	HI	DR	M	P	S	S	Unhealthy
14	Umamaheswari	26	F	C (R)	2yrs	Pneumatized	I,M (–)	STM	HD	HI	DR	A	P	S	S	Unhealthy
15	Shanthi	45	F	C (R)	2yrs	Pneumatized	I partly eroded	STM	HD	HI	DR	A	P	S	S	Unhealthy
16	Tasleem	16	F	C (L)	2yrs	Pneumatized	I,M (–)	STM	HD	HI	DR	M	P	S	S	Unhealthy
17	Alamelu	31	F	PSRP (L)	5yrs	Pneumatized	I partly eroded	STM	HD	HI	DR	PSQ	A	S	S	Unhealthy
18	Kanthamani	55	F	C (R)	2yrs	Pneumatized	I,M,S (-)	STM	HD	HI	DR	M	P	S	S	Unhealthy
19	Kumari	42	F	C (R)	2yrs	Pneumatized	I,M,S (-)	STM	HD	HI	DR	M	P	S	S	unhealthy
20	Sangeetha	33	F	PSRP (L)		Pneumatized	I partly eroded	STM	HD	HI	DR	PSQ	A	S	S	Unhealthy
21	Nithayanamtha	24	M	C (R)	1yr	Pneumatized	I,M (–)	STM	HD	HI	DR	M	P	S	S	unhealthy
22	Indirani	60	F	C (R)	5yrs	Pneumatized	I,M,S (-)	STM	HD	HI	DR	M	P	S	S	Unhealthy
23	Rubini	16	F	AP (L)	2yrs	Pneumatized	I,M,S (-)	STM	HD	HI	DR	M	P	S	S	Unhealthy
24	Manimehalai	19	F	C (L)	2 yrs	Pneumatized	I,M (–)	STM	HD	HI	DR	M	P	S	S	Unhealthy
25	Divya	15	F	C (R)	2yrs	Pneumatized	I,M (–)	STM	HD	HI	DR	A	P	S	S	Unhealthy
26	Praveen	15	M	C (L)	5yrs	Pneumatized	I,M,S (-)	STM	HD	HI	DR	A	P	S	S	Unhealthy

S. No.	Name	Age	Sex	Clinical Diagnosis	Duration of Disease	Preoperative radiological Findings							Intraoperative findings			
						Pneumatisation of mastoid	Ossicular status	HRCT	T1	T2	DWI	E	C	E	Ossicular status	Mucosal status
27	Arumugam	25	M	PSRP(R)		Pneumatized	I partly eroded	STM	HD	HI	DR	PSQ	A	S	S	Unhealthy
28	Vivek	22	M	C (R)	1yr	Pneumatized	I partly eroded	STM	HD	HI	DR	M	P	S	S	Unhealthy
29	Ganesh	26	M	C (L)	2yrs	Pneumatized	I,M (–)	STM	HD	HI	DR	A	P	S	S	Unhealthy
30	Sivaramen	22	M	C (L)	2yrs	Pneumatized	I,M,S (-)	STM	HD	HI	DR	A	P	S	S	Unhealthy
31	Dhanasekar	19	M	C (R)	1yr	Pneumatized	I,M (–)	STM	HD	HI	DR	A	P	S	S	Unhealthy
32	Sakthikumar	28	M	C (R)	1yr	Pneumatized	I,M (–)	STM	HD	HI	DR	A	P	S	S	Unhealthy
33	Vignesh	16	M	C (L)	5yrs	Pneumatized	I,M,S (-)	STM	HD	HI	DR	A	P	S	S	Unhealthy
34	Velu	35	M	C (R)	5yrs	Pneumatized	I,M,S (-)	STM	HD	HI	DR	M	P	S	S	Unhealthy
35	Manivanan	36	M	C (L)	1yr	Pneumatized	I partly eroded	STM	HD	HI	DR	M	P	S	S	Unhealthy
36	Mohan	45	M	C (L)	1yr	Pneumatized	I fully eroded	STM	HD	HI	DR	M	P	S	S	Unhealthy
37	Manju	16	F	C (L)	2yrs	sclerosed	I,M (–)	STM	HD	HI	DR	A	P	S	S	Unhealthy
38	Suganya	21	F	C (L)	2yrs	Pneumatized	I,M (–)	STM	HD	HI	DR	A	P	S	S	Unhealthy
39	Rajeswari	28	F	C (R)	5yrs	Pneumatized	I,M (–)	STM	HD	HI	DR	A	P	S	S	Unhealthy
40	Nagalingam	35	M	C (R)	1yr	Pneumatized	I fully eroded	STM	HD	HI	DR	M	P	S	S	Unhealthy
41	Madhavan	37	M	C (R)	2yr	Pneumatized	I fully eroded	STM	HD	HI	DR	M	P	S	S	Unhealthy
42	Rajendran	26	M	C (L)	2yrs	Pneumatized	I,M,S (-)	STM	HD	HI	DR	M	P	S	S	Unhealthy
43	Ravi	26	M	C (L)	2yrs	Pneumatized	I,M,S (-)	STM	HD	HI	DR	M	P	S	S	Unhealthy
44	Jothika	14	F	C (R)	1yr	Pneumatized	I,M (–)	STM	HD	HI	DR	M	P	S	S	Unhealthy
45	Dhanasekar	41	M	PSRP (L)	1yr	Pneumatized	I partly eroded	STM	HD	HI	DR	PSQ	A	S	S	unhealthy
46	Suresh	14	M	AP (L)	2yr	Pneumatized	I,M (–)	STM	HD	HI	DR	A	P	S	S	Unhealthy
47	Arul	35	M	AP (R)	5yrs	Pneumatized	I,M,S (-)	STM	HD	HI	DR	A	P	S	S	Unhealthy
48	Sumathy	19	F	C (R)	5yrs	Pneumatized	I,M,S (-)	STM	HD	HI	DR	M	P	S	S	Unhealthy
49	Asha	45	F	C (R)	2yr	Pneumatized	I,M (–)	STM	HD	HI	DR	M	P	S	S	Unhealthy
50	Rani	45	F	C (L)	5yrs	Pneumatized	I,M,S (-)	STM	HD	HI	DR	M	P	S		unhealthy

KEY WORDS TO MASTER CHART

STM	–	Soft Tissue Mass
HD	–	Hypodense
HI	–	Hyperintense
DWI	–	Diffusion Weighted Images
DR	–	Diffusion Restriction
M	–	Mastoid
A	–	Attic
C	–	Cholesteatoma
AP	–	Aural Polyp
P	–	Present
A	–	In Intraoperative is Absent
PSRP	–	Posterior Superior Retraction Pocket
PSQ	–	Posterior Superior Quadrant
GR	–	Granulation Tissue
I	–	Incus
M	–	Malleus
S	–	Stapes
(R)	–	Right Side
(L)	–	Left Side

INFORMATION SHEET

- We are conducting a prospective cohort study **“on CORRELATING PREOPERATIVE RADIOLOGICAL (HRCT AND MRI DWI)IMAGING IN PATIENTS WITH SQUAMOUS EPITHELIAL CHRONIC OTITIS MEDIA WITH PEROPERATIVE FINDING** at the Upgraded Institute of Otorhinolaryngology, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai – 600003

- Patients with squamous epithelial type of chronic otitis media are enrolled in the study they will b undergoing HRCT and MRI DWI along with other routine blood investigations and will be proceeded with surgery

- At the time of announcing the results and suggestions, name and identity of the patients will be confidential.

- Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.

- The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of Investigator **Signature of Participant**

Date :

PATIENT CONSENT FORM

Title of the Project : on PREOPERATIVE RADIOLOGICAL (HRCT AND MRI DWI) FINDINGS IN PATIENTS WITH SQUAMOUS EPITHELIAL CHRONIC OTITIS MEDIA AND CORRELATE WITH INTRAOPERATIVE FINDING

Institution : Upgraded Institute of Otorhinolaryngology,
Madras Medical College,
Chennai – 600003.

Name : Date :

Age : IP No. :

Sex : Project Patient No. :

The details of the study have been provided to me in writing and explained to me in my own language.

I confirm that I have understood the above study and had the opportunity to ask questions.

I understood that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected.

I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

I have been given an information sheet giving details of the study.

I fully consent to participate in the above study.

_____	_____	_____
Name of the subject	Signature	Date
_____	_____	_____
Name of the Investigator	Signature	Date

ஆராய்ச்சி தகவல்தாள்

சென்னை இராஜீவ்காந்தி அரசு மருத்துவமனைக்கு வரும் ஸ்குமஸ் எபிதிலியல் க்ரோனிக் ஆடைடிஸ் மிடியா உள்ள நோயாளிகளுக்கு அறுவை சிகிச்சை முன் எடுக்கப்படும் எச்.ஆர்.சி.டி. மற்றும் எம்.ஆர்.ஐ.டி.வெ.இ.-ன் முடிவுகளை அறுவை சிகிச்சையின் போது ஒப்பிட்டு பார்க்கும் ஆய்வு.

இந்த ஆராய்ச்சியில் ஸ்குமஸ் எபிதிலியல் க்ரோனிக் ஆடைடிஸ் மிடியா உள்ள நோயாளிகள் எச்.ஆர்.சி.டி., எம்.ஆர்.ஐ.டி.வெ.இ. மற்றும் பிற இரத்தப் பரிசோதனைகளுக்கு உட்படுத்தப்படுவார்கள். அதன் பின் அவர்களுக்கு அறுவை சிகிச்சை செய்யப்படும்.

நீங்கள் இந்த ஆராய்ச்சியில் பங்கேற்க நாங்கள் விரும்புகிறோம்.

இந்த ஆராய்ச்சியின் முடிவுகளை அல்லது கருத்துக்களை வெளியிடும்போதோ அல்லது ஆராய்ச்சியின் போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிடமாட்டோம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் தான் இருக்கிறது. மேலும் நீங்கள் எந்நேரமும் இந்த ஆராய்ச்சியிலிருந்து பின் வாங்கலம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியின் முடிவுகளை ஆராய்ச்சியின் போது அல்லது ஆராய்ச்சியின் முடிவின் போது தங்களுக்கு அறிவிக்கப்படும் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம் பங்கேற்பாளர் கையொப்பம்

தேதி :

சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு

ஸ்குமஸ் எபிதிலியல் க்ரோனிக் ஆடைடிஸ் மிடியா உள்ள நோயாளிகளுக்கு அறுவை சிகிச்சை முன் எடுக்கப்படும் எச். ஆர். சி.டி. மற்றும் எம்.ஆர்.ஐ.டி.வெ.இ இன் முடிவுகளை அறுவை சிகிச்சையின் போது ஒப்பிட்டு பார்க்கும் ஆய்வு.

ஆராய்ச்சி நிலையம் : ராஜீவ் காந்தி அரசு
பொது மருத்துவமனை,
சென்னை மருத்தவக் கல்லூரி,
சென்னை -600003.

பங்கு பெறுபவரின் பெயர் :

பங்கு பெறுபவரின் எண் :

பங்கு பெறுபவரின் இதனை ( )குறிக்கவும் :

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது, என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது. ☐

நான் இவ்வாய்வில் தன்னிச்சையாகதான் பங்கேற்கிறேன். எந்த காரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகி கொள்ளலாம் என்றும் அறிந்து கொண்டேன் ☐

இந்த ஆய்வு சம்மந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன். ☐

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும் அதை பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கிறேன் ☐

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின் படி நடந்து கொள்வதுடன் இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன். என் உடல் நலம் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறான நோய்குறி தென்பட்டாலோ உடனே அதை மருத்துவ அணியிடம் தெரிவிப்பேன் என உறுதி அளிக்கிறேன். ☐

இந்த ஆய்வில் எனக்கு இரத்தம், சிறுநீர், எக்ஸ்ரே, பரிசோதனை செய்து கொள்ள நான் முழு மனதுடன் சம்மதிக்கிறேன். ☐

பங்கேற்பவரின் கையொப்பம்..... இடம்..... தேதி

கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்.....

ஆய்வாளரின் கையொப்பம் ..... இடம்.....தேதி

ஆய்வாளரின் பெயர்.....

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI 600 003

EC Reg.No.ECR/270/Inst./TN/2013
Telephone No.044 25305301
Fax: 011 25363970

CERTIFICATE OF APPROVAL

To

Dr.Savidha.C.U.
II Year PG in MS(ENT)
Upgraded Institute of Oto-Rhinolaryngology
Madras Medical College
Chennai 600 003

Dear Dr. Savidha.C.U.,

The Institutional Ethics Committee has considered your request and approved your study titled **"CORRELATING PRE-OPERATIVE RADIOLOGICAL (HRCT AND MRI - DWI) IMAGING IN PATIENTS WITH SQUAMOUS EPITHELIAL CHRONIC OTITIS MEDIA WITH PEROPERATIVE FINDINGS"** NO.30022015.

The following members of Ethics Committee were present in the meeting hold on 03.02.2015 conducted at Madras Medical College, Chennai 3.

1. Dr.C.Rajendran, MD	:Chairperson
2. Dr.R.Vimala,MD.,Dean,MMC,Ch-3	: Deputy Chairperson
3. Prof.B.Kalaiselvi,MD.,Vice Principal,MMC,Ch-3	: Member Secretary
4. Prof.R.Nandhini,MD.,Inst.of Pharmacology,MMC	: Member
5. Prof.P.Ragumani, MS., Professor, Inst.of Surgery,MMC	: Member
6. Prof.K.Ramadevi, Director , Inst.of Bio-Chem.MMC	: Member
7. Prof.Saraswathy,MD.,Director,Pathology, MMC	: Member
8. Prof.Md.Ali, MD., DM.,Prof.&HOD of Medl.GE,MD.MMC	: Member
9. Prof.S.G.Sivachidambaram,Director I/c, Inst.of Internal Medicine	: Member
10. Thiru S.Rameshkumar	: Lay Person
11. Thiru S.Govindasamy, BA., BL.,	: Lawyer
12. Tmt.Arnold Saulina, MA., MSW.,	: Social Scientist

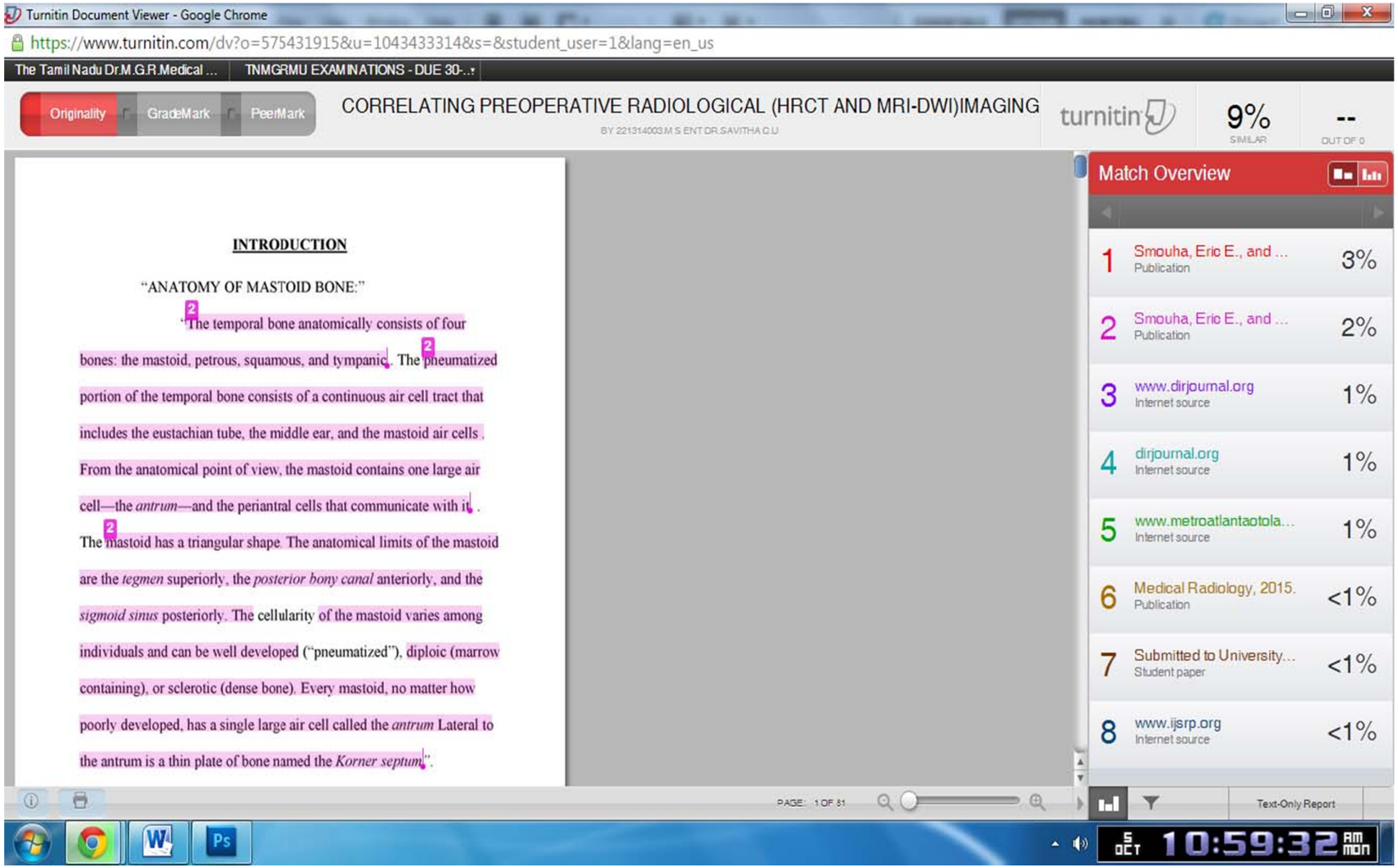
We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary, Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

Sys 2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INTRODUCTION
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"The temporal bone anatomically consists of four bones: the mastoid, petrous, squamous, and tympanic. The pneumatized portion of the temporal bone consists of a continuous air cell tract that includes the eustachian tube, the middle ear, and the mastoid air cells . From the anatomical point of view, the mastoid contains one large air cell—the antrum—and the periantral cells that communicate with it . The mastoid has a triangular shape. The anatomical limits of the mastoid are the tegmen superiorly, the posterior bony canal anteriorly, and the sigmoid sinus posteriorly. The cellularity of the mastoid varies among individuals and can be well developed ("pneumatized"), diploic (marrow containing), or sclerotic (dense bone). Every mastoid, no matter how poorly developed, has a single large air cell called the antrum Lateral to the antrum is a thin plate of bone named the Korner septum".
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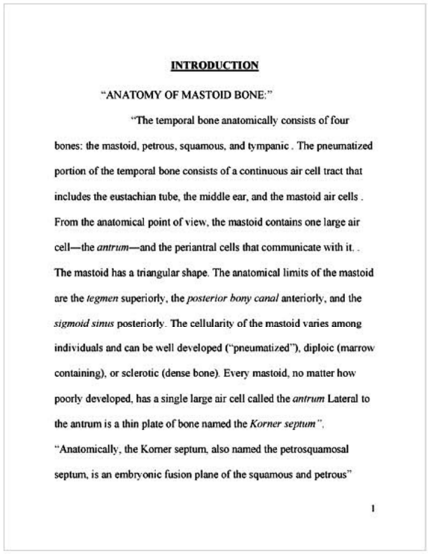

INTRODUCTION

"ANATOMY OF MASTOID BONE:"

"The temporal bone anatomically consists of four bones: the mastoid, petrous, squamous, and tympanic . The pneumatized portion of the temporal bone consists of a continuous air cell tract that includes the eustachian tube, the middle ear, and the mastoid air cells . From the anatomical point of view, the mastoid contains one large air cell—the *antrum*—and the periantral cells that communicate with it. . The mastoid has a triangular shape. The anatomical limits of the mastoid are the *tegmen* superiorly, the *posterior bony canal* anteriorly, and the *sigmoid sinus* posteriorly. The cellularity of the mastoid varies among individuals and can be well developed ("pneumatized"), diploic (marrow containing), or sclerotic (dense bone). Every mastoid, no matter how poorly developed, has a single large air cell called the *antrum* Lateral to the antrum is a thin plate of bone named the *Korner septum"*.

"Anatomically, the Korner septum, also named the petrosquamosal septum, is an embryonic fusion plane of the squamous and petrous"

1